

IN THE UNITED STATES DISTRICT COURT FOR THE  
SOUTHERN DISTRICT OF WEST VIRGINIA, HUNTINGTON DIVISION  
BEFORE THE HONORABLE ROBERT C. CHAMBERS, JUDGE

---o0o---

CLAUDE R. KNIGHT and CLAUDIA  
STEVENS, individually and as  
personal representatives of the  
Estate of BETTY ERLINE KNIGHT,  
deceased,

Plaintiffs,

vs.

No. 3:15-CV-06424

BOEHRINGER INGELHEIM  
PHARMACEUTICALS, INC.,

Volume 4  
Pages 661 through 845

Defendant.

\_\_\_\_\_/

---o0o---

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL

TUESDAY, OCTOBER 9, 2018, 9:00 A.M.

---o0o---

For the Plaintiffs: CHILDERS, SCHLUETER & SMITH  
1932 North Druid Hills Road, Ste 100  
Atlanta, Georgia 30319  
BY: C. ANDREW CHILDERS

URY & MOSKOW  
883 Black Rock Turnpike  
Fairfield, Connecticut 06825  
BY: NEAL L. MOSKOW

(Appearances continued next page...)

Reported by: KATHY L. SWINHART, CSR  
LISA A. COOK, RPR-RMR-CRR-FCRR  
Official Court Reporters  
(304) 528-2244

1 APPEARANCES (Continued)

2  
3 For the Plaintiffs:

4 FERRER, POIROT & WANSBROUGH  
2100 RiverEdge Parkway, Suite 1025  
5 Atlanta, Georgia 30328  
6 BY: RUSSELL ABNEY  
and HUNTER VANCE LINVILLE

7  
8 For the Defendant:

9 TUCKER ELLIS  
925 Euclid Avenue, Suite 1150  
10 Cleveland, Ohio 44115  
11 BY: JOHN Q. LEWIS

12 COVINGTON & BURLING  
One City Center  
13 850 Tenth Street NW  
Washington, D.C. 20001  
14 BY: PHYLLIS ALENE JONES  
and NICHOLAS HAILEY  
15 and JESSICA PEREZ

16 JACKSON KELLY  
17 Post Office Box 553  
Charleston, West Virginia 25322  
18 BY: GRETCHEN M. CALLAS

19  
20 Also Present:

21 CLAUDE R. KNIGHT, Plaintiff  
22  
23  
24  
25

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

INDEX

| <u>PLAINTIFF'S WITNESSES:</u>        | <u>PAGE :</u> |
|--------------------------------------|---------------|
| DAWN MAC FARLAND, M.D.               |               |
| VIDEOTAPED DEPOSITION PLAYED         | 662           |
| AHMED ABDELGABER, M.D.               |               |
| VIDEOTAPED DEPOSITION PLAYED         | 666           |
| JOANNE VAN RYN                       |               |
| VIDEOTAPED DEPOSITION PLAYED         | 672           |
| HAZEM ASHHAB, M.D.                   |               |
| DIRECT EXAMINATION BY MR. CHILDERS   | 674           |
| CROSS-EXAMINATION BY MR. LEWIS       | 730           |
| REDIRECT EXAMINATION BY MR. CHILDERS | 808           |
| RECROSS-EXAMINATION BY MR. LEWIS     | 830           |

1 HUNTINGTON, WEST VIRGINIA

2 TUESDAY, OCTOBER 9, 2018, 9:06 A.M.

3 THE COURT: Good morning.

4 Before we bring the jury in, I note that the defense  
5 filed a motion with respect to Dr. Ashhab's opinions. When  
6 do you expect to call him as a witness?

7 MR. CHILDERS: Right after lunch, Your Honor.

8 THE COURT: All right. Have you seen the motion?

9 MR. CHILDERS: I have.

10 THE COURT: Will you be prepared to at least argue  
11 it a little bit later this morning?

12 MR. CHILDERS: Then or now, whatever you prefer.

13 THE COURT: Well --

14 MR. CHILDERS: At any point today we can argue it.

15 THE COURT: All right. I'd rather bring the jury  
16 out. All right. Are we ready for the jury?

17 MR. CHILDERS: Yes, Your Honor.

18 (Jury returned into the courtroom at 9:08 a.m.)

19 THE COURT: Good morning. Welcome back. We're  
20 ready to have the plaintiff call their next witness.

21 MR. CHILDERS: Thank you, Your Honor.

22 Ladies and gentlemen, this is going to be another  
23 video. Plaintiffs are going to play the video of Dr. Dawn  
24 MacFarland. It's about an 18-minute video. And then the  
25 defendants will play their examination.

1           **VIDEOTAPED DEPOSITION OF DAWN MACFARLAND, PLAINTIFFS'**  
2           **WITNESS, PLAYED.**

3           (Videotaped deposition paused.)

4           MS. JONES: Your Honor, you had asked us to give  
5 folks a stretch break during some of the videos. We have a  
6 little bit left but we thought this might be an appropriate  
7 time.

8           THE COURT: All right. Take a minute. If you'd  
9 like to stretch, use the restroom, get a drink, feel free  
10 to.

11          (Pause in proceedings from 10:20 a.m. until 10:29 a.m.)

12          (Jury not present)

13          THE COURT: All right. So since the jury  
14 obviously wanted to take a little more than just a minute or  
15 two break and none of them are present in the courtroom, I'd  
16 like to take up the defense motion at least to hear the  
17 plaintiffs' response.

18          Are you ready to do that, Mr. Childers?

19          MR. CHILDERS: Yes, Your Honor.

20          THE COURT: Go ahead.

21          MR. CHILDERS: We did read this last night when it  
22 came in. I'm not going to comment on the timing of it, but  
23 I would just say that we don't intend to elicit opinions  
24 from Dr. Ashhab relating to these two issues. But these are  
25 facts that things are or are not in the label. And I do

1 expect him to testify, yes, they are, or, no, they're not in  
2 the label, but he's not going to offer an opinion as to  
3 whether or not it should have been in the label.

4 MR. LEWIS: I guess, Your Honor, that's what,  
5 that's what the concern is. Dr. Ashhab did not mention  
6 either in his report or in his deposition that there's any  
7 criticism of the label whatsoever for those purposes. I  
8 don't think that he ought to be able to just float in the  
9 suggestion or imply to the jury that there's a deficiency  
10 because of that.

11 THE COURT: How would those facts be relevant to  
12 his opinions if they weren't facts he relied upon in  
13 reaching his opinion?

14 MR. CHILDERS: Well, he relied on the entirety of  
15 the label, both -- all of the labels. And we disclosed  
16 that, that he looked at all of them.

17 THE COURT: And that's fine. He can testify --

18 MR. CHILDERS: Right.

19 THE COURT: -- that the label doesn't say that  
20 this was tested on severe, severely compromised renal  
21 patients or that the 75-milligram dose was tested.

22 MR. CHILDERS: Correct.

23 THE COURT: So I think he can do that.

24 MR. LEWIS: Okay. I guess, Your Honor, I just, if  
25 I may, I think it's very misleading to the jury based on the

1 way that they've presented the case thus far for Dr. Ashhab  
2 to mention those facts in the same context where he's  
3 criticizing the label in a general way, particularly when it  
4 was never -- and they could have disclosed this to us. That  
5 could have been a criticism of Dr. Ashhab. He could have  
6 mentioned that fact during his deposition or in his report.  
7 It's nowhere to be found in anything that he said to date.

8 And it will be very misleading to this jury to, to  
9 shoehorn in those facts into a general criticism of our  
10 label. I don't think it's relevant to his opinion. They're  
11 not facts that he relied upon or ever mentioned. And I  
12 don't think he should be permitted to even mention it.

13 MR. CHILDERS: Facts are facts, Judge. I'm not  
14 really sure how he can talk about the label and not, and not  
15 be allowed to talk about particular parts.

16 Again, I'm not going to elicit any opinion from him it  
17 should have been in there, it shouldn't have been in there.  
18 This is the information that Dr. MacFarland had when she  
19 made the decision to prescribe it. This is the information  
20 that the patients -- well, actually, he's not even going to  
21 talk about the Medication Guide on that issue. It just --  
22 that's the information she had when she made the decision.  
23 That's, that's the limit of where we're going to go with  
24 that.

25 THE COURT: Well, I want to think about it. I may

1 have some more inquiry before we get to it. When do you  
2 expect to get to him?

3 MR. CHILDERS: We're going to play Dr.  
4 Abdelgaber's deposition after this. And then he would be  
5 the next witness I assume right after we take our lunch  
6 break, Your Honor.

7 THE COURT: How long is Dr. Abdelgaber's  
8 deposition?

9 MR. CHILDERS: Our portion, Your Honor, is 47  
10 minutes and the defense is 30 minutes.

11 THE COURT: Okay, all right. Well, I want to  
12 think about it. We may have some more argument when we take  
13 the break.

14 MR. CHILDERS: Yes, sir.

15 THE COURT: Let's see if the jury is ready.

16 (Jury returned into the courtroom at 10:33 a.m.)

17 THE COURT: All right. We're ready to resume.

18 (Videotaped deposition resumed.)

19 (Videotaped deposition paused.)

20 MS. JONES: That's the conclusion of the defense  
21 examination.

22 THE COURT: All right.

23 MR. CHILDERS: We have an extremely short  
24 redirect. Don't blink. It's only 25 seconds long.

25 THE COURT: Go ahead.

1 (Videotaped deposition resumed.)

2 THE COURT: All right.

3 MR. CHILDERS: That it.

4 THE COURT: All right. Call your next witness.

5 MR. CHILDERS: Again, I apologize. We have  
6 another video. This will be Dr. Abdelgaber. And our play  
7 of this, Your Honor, is about 45 minutes long.

8 THE COURT: Okay.

9 **VIDEOTAPED DEPOSITION OF AHMED ABDELGABER, PLAINTIFFS'**  
10 **WITNESS, PLAYED.**

11 (Videotaped deposition paused.)

12 MR. CHILDERS: This might be a good time for a  
13 stretch.

14 THE COURT: All right. If you want to stand up  
15 and stretch where you're seated, that would be fine.

16 (Pause in proceedings)

17 THE COURT: How many more minutes on the direct  
18 side of this?

19 MR. CHILDERS: I think about 15 more minutes.

20 THE COURT: Okay. All right, let's get started.

21 (Videotaped deposition resumed.)

22 (Videotaped deposition paused.)

23 MR. CHILDERS: That's the end of the plaintiffs'  
24 direct, Your Honor.

25 THE COURT: All right.

1 MR. LEWIS: Your Honor, we'll do the defense play  
2 at this time.

3 THE COURT: You may proceed.

4 (Videotaped deposition resumed.)

5 (Videotaped deposition paused.)

6 MR. LEWIS: Your Honor, that concludes the defense  
7 portion.

8 THE COURT: All right.

9 MR. CHILDERS: We have again another very short  
10 redirect, one minute long.

11 THE COURT: Go ahead.

12 (Videotaped deposition resumed.)

13 THE COURT: All right. That concludes Dr.  
14 Abdelgaber's testimony?

15 MR. CHILDERS: Yes, sir.

16 THE COURT: All right. This is a good time for us  
17 to take a break, ladies and gentlemen. We're going to take  
18 a lunch recess for one hour. I'd like you back here at  
19 1:00.

20 Remember my instructions from last week. Don't discuss  
21 the case with anyone or allow anyone to discuss it with you.  
22 Make sure you have your stickers as you go and as you depart  
23 the courthouse, and then return and please go to the jury  
24 room.

25 All right. If there's nothing else, I'm going to let

1 the jury go first. I have a matter to take up with counsel  
2 as soon as the jury leaves.

3 (Jury retired from the courtroom at 12:03 p.m.)

4 THE COURT: All right. You may be seated.

5 Is there anything else counsel wants to bring to my  
6 attention about the pending motion regarding Dr. Ashhab's  
7 testimony?

8 MR. CHILDERS: No, Your Honor.

9 MR. LEWIS: No, Your Honor.

10 THE COURT: Well, as I understand it, first, the  
11 defendant's written motion sought to prohibit Dr. Ashhab  
12 from being asked or giving opinions related to, first,  
13 whether the label was inadequate because it did not reveal  
14 that Pradaxa had not been tested on patients who had severe  
15 renal impairment; secondly, that the label was -- in the  
16 opinion that the label was defective because the label did  
17 not reflect whether or not testing had been done at the  
18 75-milligram dose.

19 In response, plaintiffs indicate they don't intend to  
20 ask Dr. Ashhab for opinions that would be critical of the  
21 label for the absence of that information but, instead,  
22 merely intended to ask him whether as a fact he was aware  
23 that the label did not address testing for -- on patients  
24 with renal, severe renal impairment or testing at the 75  
25 dose.

1 In response, defendants argue that that would be  
2 misleading or confusing to the jury because there would be  
3 no reason for Dr. Ashhab to mention those two facts unless  
4 he was offering an opinion or an inference critical of the  
5 company's labeling.

6 I agree with the defendant. The Court has reviewed not  
7 only the motion but the entire deposition of Dr. Ashhab, as  
8 well as his report.

9 First, I would find -- I accept plaintiffs'  
10 representation that they didn't ask -- intend to ask him  
11 specific opinions critical of the label. And that certainly  
12 wasn't part of his report or even noted in his deposition.

13 Beyond that, I would find that I agree with the  
14 defendants that it would either be cumulative and/or  
15 confusing or misleading to the jury for Dr. Ashhab to  
16 testify as to the fact about the labels not having this  
17 information with the testing.

18 First, obviously, he didn't even explain in his report  
19 or his deposition that he was familiar at that level with  
20 the testing. There's other evidence from Dr. Plunkett, as  
21 well as the label itself, that establishes what the label  
22 had and whether it should have had more information about  
23 the underlying testing.

24 So I think it would be cumulative for Dr. Ashhab to  
25 merely note what's already established by the evidence, and

1 that is that the label does not specifically note that there  
2 was no testing of severely impaired renal patients nor  
3 testing specifically of the 75 dose.

4 So I think it would be cumulative and misleading  
5 because he's an expert and he's going to be critical of the  
6 defendant's product for a variety of reasons which he  
7 explains in his report and his deposition.

8 And I believe it would be difficult for the jury to not  
9 also find that Dr. Ashhab is at least implicitly critical of  
10 the label in these two respects. And for the reasons I've  
11 stated, I think that's beyond the scope of his opinion.

12 So I would restrict plaintiffs on those areas and  
13 expect you to inform him before he testifies.

14 MR. CHILDERS: Understood, Your Honor. Thank you.

15 THE COURT: All right. Is he going to be next up?

16 MR. CHILDERS: Yes, sir. I believe he's in route  
17 right now from Charleston, so as long as the traffic is --

18 THE COURT: Okay. Well, good luck. And then  
19 after him, what do you -- any idea how long your direct will  
20 take?

21 MR. CHILDERS: I'm hoping that my direct takes  
22 about an hour, hour and a half.

23 THE COURT: Okay. Who is going to cross him?

24 MR. LEWIS: I will, Your Honor.

25 THE COURT: Any idea?

1 MR. LEWIS: About the same. I definitely don't  
2 want to go longer than they do on direct.

3 THE COURT: All right. Then after him --

4 MR. CHILDERS: If, if we finish and have time  
5 today we have another video to play of a Boehringer  
6 employee, Dr. Van Ryn.

7 THE COURT: All right. I'll see you back here at  
8 1:00.

9 (Recess taken from 12:08 p.m. until 1:03 p.m.)

10 (Jury not present.)

11 THE COURT: Is he out checking on his witness?

12 MR. MOSKOW: Sorry, Your Honor.

13 THE COURT: So I'm going to move the sentencing  
14 that I had scheduled for later today, so it's no longer a  
15 factor. If, if he's not close or ready, if you want to do  
16 the video first, you may do so.

17 MR. CHILDERS: It looks like he's about 10 minutes  
18 away.

19 THE COURT: That's like 10 minutes to get here?

20 MR. CHILDERS: Yes, sir.

21 THE COURT: Well, by the time he parks and does  
22 things, so let's go ahead and do the video. And then if we  
23 have to stay a little bit later, I no longer have the  
24 sentencing. So --

25 MR. LEWIS: We think it makes sense to play the

1 video all the way through.

2 THE COURT: Yeah, we will, right.

3 MR. LEWIS: Thank you, Your Honor.

4 THE COURT: It's how long?

5 MR. MOSKOW: Forty minutes total.

6 THE COURT: Okay, great. Bring the jury in.

7 (Jury returned into the courtroom at 1:05 p.m.)

8 THE COURT: All right, ladies and gentlemen, we're  
9 ready to resume. The plaintiffs have literally in route one  
10 of their expert witnesses, Dr. Ashhab, but he's not quite  
11 here yet.

12 So plaintiffs' counsel has suggested, and I agree, that  
13 they proceed with a video deposition that they were going to  
14 introduce into evidence anyway. And so that we don't have  
15 you all sitting back there waiting 15 or 20 minutes, we'll  
16 just proceed with the video.

17 MR. CHILDERS: Thank you, Your Honor. This will  
18 be the deposition of Joanne Van Ryn, a Boehringer employee.  
19 And I think our play is around 18 minutes long.

20 **VIDEOTAPED DEPOSITION OF JOANNE VAN RYN, PLAINTIFFS'**  
21 **WITNESS, PLAYED.**

22 (Videotaped deposition paused.)

23 MR. MOSKOW: Your Honor, that concludes the  
24 plaintiffs' play of Dr. Van Ryn.

25 THE COURT: All right.

Hazem Ashhab - Direct (Childers)

1 MR. LEWIS: Your Honor, we'll do the defense play  
2 at this time.

3 THE COURT: Go ahead.

4 (Videotaped deposition resumed.)

5 (Videotaped deposition paused.)

6 MR. LEWIS: That concludes the defense play, Your  
7 Honor.

8 THE COURT: All right. Are we finished with that?

9 MR. CHILDERS: Yes, Your Honor. We don't have  
10 anymore.

11 THE COURT: All right. Why don't we go ahead and  
12 take a brief recess. The next witness is Dr. Ashhab, a live  
13 witness?

14 MR. CHILDERS: That's correct, Your Honor.

15 THE COURT: And so as to avoid an interruption to  
16 that, let's take about a five-minute recess, be pretty  
17 quick.

18 (Recess taken from 1:48 p.m. until 1:53 p.m.)

19 THE COURT: All right. Are we ready to proceed?

20 MR. CHILDERS: Yes, Your Honor.

21 THE COURT: Let's bring the jury out.

22 (Jury returned into the courtroom at 1:53 p.m.)

23 THE COURT: All right, plaintiffs may call their  
24 next witness.

25 MR. CHILDERS: Your Honor, plaintiffs call

Hazem Ashhab - Direct (Childers)

674

1 Dr. Ashhab.

2 THE COURT: All right.

3 Dr. Ashhab, if you'll step up here, my clerk will  
4 administer the oath.

5 **HAZEM ASHHAB, PLAINTIFFS' WITNESS, SWORN**

6 DIRECT EXAMINATION

7 BY MR. CHILDERS:

8 Q. Doctor, just so you know, the acoustics in here are not  
9 great, so you have to speak into the microphone. Okay?

10 A. Okay.

11 Q. Would you please introduce yourself to the jury?

12 A. My name is Dr. Ashhab. I'm a gastroenterologist  
13 specializing in internal medicine and gastroenterology and  
14 liver disease.

15 I'm Board Certified and recertified in  
16 gastroenterology. I'm part of a private practice affiliated  
17 with the University, WVU, and with Charleston Area Medical  
18 Center in Charleston, West Virginia. We are partners of  
19 six.

20 Q. Let me stop you there and sort of break that up a  
21 little bit if I could. Do you practice -- you practice here  
22 in West Virginia?

23 A. Yes.

24 Q. And where is your practice?

25 A. In Charleston, West Virginia.

1 Q. And what kind of a practice is it?

2 A. It's a single specialty practice where all six of us  
3 are gastroenterologists or Board Certified in  
4 gastroenterology.

5 Q. Could you explain to the jury what gastroenterology  
6 means?

7 A. So --

8 Q. We're not doctors, so if you could explain to us.

9 A. So gastroenterology is the specialty in internal  
10 medicine where you deal with patients with digestive disease  
11 disorders including the stomach, the bowels, the colon, the  
12 liver, the pancreas.

13 We deal with patients with symptoms related to these  
14 organs including problems with swallowing, problems with the  
15 liver, and bleeding as well.

16 Q. That was my next question. Do you treat patients who  
17 have GI bleeds or gastrointestinal bleeds?

18 A. Very frequently.

19 Q. How often would you estimate you do that?

20 A. Almost on a daily basis, at least twice a week.

21 Q. So let me ask you another question. In addition to  
22 your medical practice, do you treat patients at hospitals?

23 A. Yes. We, we are the only group that covers Charleston  
24 Area Medical Center, CAMC, including Memorial and General  
25 divisions and Women and Children for anybody in relation to

1 bleeding or gastrointestinal disorders. I do also have  
2 privileges and do out-patient procedures at Charleston  
3 Surgical Hospital.

4 Q. Okay. How long have you lived and practiced medicine  
5 here in West Virginia?

6 A. Seventeen years.

7 Q. You mentioned you were Board Certified; --

8 A. Yes.

9 Q. -- is that right? And you have Board Certifications in  
10 two different areas of medicine?

11 A. Gastroenterology is a subspecialty of medicine. So you  
12 have to do training and complete your training, get Board  
13 Certified in internal medicine, and then you go into  
14 gastroenterology as a subspecialty.

15 Q. What do you have to do to be Board Certified? What  
16 does that mean?

17 A. So you have to go into a training program that is  
18 approved and accredited by the American Board of Internal  
19 Medicine. And you go through testing and training for a  
20 minimum of three years in internal medicine.

21 And after you pass your exams and evaluations you get a  
22 certificate that you are Board eligible. So at this point,  
23 you have a certificate that you specialize in internal  
24 medicine, and then you go to sit before the Board.

25 And the American Board is a national exam. Same

1 questions, same standards are applied to all physicians from  
2 coast to coast.

3 Q. So you have to become Board eligible by education and  
4 training and then you take a test to become Board Certified?

5 A. Correct.

6 Q. And when did you become Board Certified in internal  
7 medicine?

8 A. In 1994.

9 Q. And when did you become Board Certified in  
10 gastroenterology?

11 A. In 1998.

12 Q. And did you have to renew that again?

13 A. Yes. In 2009 I renewed it and the certificate was  
14 issued in 2010. So it is valid for 10 more years. We  
15 recertify every 10 years.

16 Q. Okay. And when you recertify, what do you have to do?

17 A. You do things all over again. You basically have to,  
18 to study. And sometimes you go through courses. Sometimes  
19 you do it on-line. And then you go sit for the exam.

20 Q. Okay. Did you treat patients, gastroenterology  
21 patients in Charleston last week?

22 A. Yes.

23 Q. How about this week? Did you treat patients today?

24 A. Yes.

25 Q. Okay. And I understood --

1 A. Before coming to court.

2 Q. And I understood you had a couple maybe that came in  
3 unexpectedly and you were there longer than you expected to  
4 be this morning?

5 A. Yes. A gentleman came with bleeding actually last  
6 night, so I had to take care of him today.

7 Q. And then when you leave here after you testify, are you  
8 going to go back and treat patients there tomorrow?

9 A. Maybe even tonight.

10 Q. Okay. Depending on what time we let you go?

11 A. Because I'm on call, yeah. I told them 6:00, so I hope  
12 I get there before 6:00 but --

13 Q. Have you ever treated a patient who had a GI bleed who  
14 you believed it was caused by Pradaxa?

15 A. Yes, more than one time.

16 Q. And you understand that's why we're here today to talk  
17 about a patient who had a GI bleed while she was on Pradaxa;  
18 right?

19 A. Yes.

20 Q. And did you review Betty Knight's medical records in  
21 forming your opinions?

22 A. Yes.

23 Q. Did you review the depositions of her doctors that were  
24 taken in the case before you formed your opinions?

25 A. Yes.

Hazem Ashhab - Direct (Childers)

679

1 Q. Okay. I want to walk through a couple of those records  
2 with you right now. You have in front of you a binder. If  
3 you could go to the tab that's 2000-A, do you see that?

4 A. Yes.

5 Q. If you would turn to Page 26 at the top, on the top  
6 right corner.

7 A. Yes.

8 Q. Okay.

9 MR. CHILDERS: And, Your Honor, I probably should  
10 have done this previously. We have agreed on a  
11 comprehensive medical examination exhibit, Exhibit Number  
12 2000. These are taken from that. We'd move 2000 into  
13 evidence at this point.

14 THE COURT: Any objection?

15 MR. LEWIS: No objection, Your Honor.

16 THE COURT: It's admitted and it may be published.

17 MR. CHILDERS: Thank you, Your Honor.

18 (Plaintiffs' Exhibit Number 2000 admitted into  
19 evidence.)

20 BY MR. CHILDERS:

21 Q. Do you see, Doctor, this is the History and Physical  
22 from May 20th, 2013, for Ms. Knight?

23 A. Yes.

24 Q. Can you explain to the jury what a History and Physical  
25 is?

1 A. When a patient comes to the hospital, whether to the  
2 emergency room or otherwise, usually a house officer or a  
3 specialist or a hospitalist will interview them for the  
4 first time.

5 They will obtain detailed medical history of the  
6 patient on why they are coming this time, what pre-existing  
7 conditions or medical history they had in the past, review  
8 their medications, and then perform a thorough physical  
9 examination.

10 Based on that, they will order some lab testing or  
11 imaging test to help them in reaching the diagnosis. And  
12 then they put a set of orders regarding management.

13 And from that point on, the care is directed according  
14 to that assessment, whether the patient goes to the floor or  
15 to the intensive care unit and so on and so forth.

16 Q. This particular record is dictated by Dr. Abdelgaber.  
17 Do you see that?

18 A. Yes.

19 Q. And the jury this morning heard his and watched his  
20 deposition. He talked about this record, so I don't need to  
21 go in great detail with you. But if you could, tell us what  
22 was the reason why Ms. Knight was going to the hospital that  
23 day?

24 A. Because she experienced GI bleeding. She had blood  
25 mixed with her stool and that made her feel weak, went to

1 her doctor. She had blood and lots of blood clots.

2 Q. Okay. And in your experience, is that the kind of GI  
3 bleed that you would treat?

4 A. Yes.

5 Q. And as you reviewed the records, did you also see  
6 that -- how long she stayed in the hospital for that  
7 particular visit?

8 A. I believe over two weeks.

9 Q. Okay. And if we could, I want to take you to Page 32  
10 in that same exhibit. Do you see this is a Discharge  
11 Summary from that hospitalization?

12 A. Yes.

13 Q. Okay. And tell the jury, if you would, what's the  
14 purpose of a Discharge Summary?

15 A. It summarizes the, the hospital stay of the patient  
16 including when did they come in, how did they progress  
17 during the hospital stay, and what is their final plan of  
18 disposal.

19 And it should reflect whether the patient had  
20 medications, blood transfusions, surgeries or procedures.  
21 It should reflect the outcome, whether the patient gets  
22 better or worse.

23 Q. Okay. And if you could, if we could look at the  
24 Discharge Diagnoses.

25 Could you call up the first three?

1           What were the, the diagnoses, the first three diagnoses  
2   on this Discharge Summary?

3   A.    Severe gastrointestinal blood loss anemia, was  
4   symptomatic initially; lower gastrointestinal blood loss,  
5   likely colonic AVM bleeding, status-post colonoscopy and  
6   clipping. Number three is atrial fibrillation on Pradaxa.

7   Q.    Okay. Do you see anything in this Discharge Diagnoses  
8   that mentions Plavix?

9   A.    No.

10   Q.    Okay. And then I want to sort of get a general -- ask  
11   you a general question and then we can sort of walk through  
12   the records to get more information.

13           Based on what you have reviewed in all of the records,  
14   Doctor, and the depositions that you read and your training  
15   and experience as a gastroenterologist, have you formed any  
16   opinions on what was the most significant cause of Betty  
17   Knight's gastrointestinal bleed in May of 2013?

18   A.    Most likely, the severity of her bleeding was related  
19   to the intake of Pradaxa.

20   Q.    And have you -- and based on the records you've looked  
21   at, and we'll break it down after we talk about it more  
22   generally, did you form any opinion on whether or not she  
23   was over-anticoagulated or had too much Pradaxa in her  
24   blood?

25   A.    I believe she did.

1 Q. Okay. Well, let's start with Betty herself as a  
2 patient. What is it about Betty Knight that would lead you  
3 to believe that she's a patient who would likely be  
4 over-anticoagulated on Pradaxa?

5 A. Well, she has the risk factors for having too much of  
6 the drug in her system, including her age, above 65, -- in  
7 her case she's above 80 -- a female, has compromised kidney  
8 function test.

9 Also in this particular incidence one of the  
10 medications she was taking, namely Coreg, would have  
11 affected the level of her blood thinner, the Pradaxa, by  
12 making more of the blood -- of the medication stay in her  
13 system being a P-gp inhibitor.

14 Q. The jury has heard that term and I actually put the  
15 board back up for them just in case while we're doing this  
16 examination. Could you explain, as best you can, what does  
17 that mean if a drug is a P-gp inhibitor?

18 A. Well, P-gp stands for permeability glycoprotein. So  
19 this is like a vehicle that transports certain medications  
20 across membranes between cells in the plasma.

21 So if that vehicle is interrupted, it's not going to  
22 carry the medication where it's supposed to go. So if you  
23 have -- the studies have found that certain medications that  
24 inhibit that vehicle or make it not work will result in some  
25 of these medications being too high in the system or too

1 high in the blood, so they are not eliminated properly.

2 That may lead to a high level in the blood.

3 It has also been associated with other conditions that  
4 may not be relevant to this, but it can also affect your  
5 body response to certain antibiotics. So some people will  
6 not respond to certain antibiotics because of problems with  
7 that transporter. So it's an important vehicle in the, in  
8 the human body.

9 Q. Okay. And so if I understood you correctly, the, the  
10 things about Betty that make you think that she's likely to  
11 be over-anticoagulated were that she's over 80; she's a  
12 female; she had severe kidney impairment; and she was taking  
13 Coreg, which is a P-gp inhibitor drug. Is that right?

14 A. That's correct.

15 Q. What -- do you know what Coreg is used to treat?

16 A. It's a beta blocker. It's used for blood pressure and  
17 rapid heart rate in people with heart disease.

18 Q. Is that common medication that you would see in an  
19 atrial fibrillation patient?

20 A. Yes.

21 Q. Beyond Betty herself, did you see any test results or  
22 anything in the medical records that indicated to you that  
23 Betty had too much Pradaxa in her system when she had this  
24 bleed in May of 2013?

25 A. Well, unfortunately, there wasn't any precise test

Hazem Ashhab - Direct (Childers)

685

1 given to measure Pradaxa. However, the closest or the rough  
2 blood test that was available and mentioned in her records  
3 is called the aPTT which seemed to be significantly  
4 elevated, although the record reflects that she had stopped  
5 taking the medication more than 24 hours prior to the test  
6 and she had received a blood transfusion which should have  
7 helped in correcting that abnormality but instead was  
8 elevated. So I would say it must have been overly  
9 anticoagulated.

10 Q. Okay. And so if we could just sort of break that down  
11 a little for the jury, she had an aPTT test which we've got  
12 that on the board too. That's one of these coagulation  
13 tests you can give a patient; is that right?

14 A. That's correct.

15 Q. And that test wasn't given right when she came in the  
16 hospital; is that correct?

17 A. It seems that it was done more than 24 hours after  
18 that.

19 Q. Okay. It was the second day she was in the hospital?

20 A. After she received blood transfusion.

21 Q. Why is that important as far as testing the level of  
22 coagulation in her blood that it was more than 24 hours  
23 after her last Pradaxa dose?

24 A. Well, because you, you would, you would think, I  
25 mean -- well, not you would think. You know that if you

1 have not taken the medication for so long, the medication  
2 level should have been down significantly or eliminated most  
3 of it depending on the half-life.

4 So if you go back 24 hours prior or you do the test  
5 when she actually took the medication, then it will be much  
6 higher than what you measure 24 hours later.

7 Q. Okay. And in this case, they just happened to not  
8 measure it the day she came in; is that right?

9 A. That's what we have in the record.

10 Q. Okay. What about the amount of bleeding she had? Was  
11 there anything about that that factored into your opinion on  
12 whether she was over-anticoagulated?

13 A. Well, it was a life-threatening bleed. She had lost  
14 almost -- more than five grams of hemoglobin. It went down  
15 to a hemoglobin of 6. That's life-threatening. She had  
16 acquired a total of four units of blood transfusion. I  
17 would say, you know, that's life-threatening.

18 If you put these two factors in somebody who's not 40  
19 or 50, who's 83 and has heart disease and has diabetes and  
20 has had a stroke, you better believe it's life-threatening.

21 Q. Okay. You mentioned that we didn't have a precise  
22 measurement of Betty's Pradaxa level. Do you recall that?

23 A. That's correct.

24 Q. And as a doctor who treats patients with GI bleeds,  
25 does Boehringer provide you with any information as to how

Hazem Ashhab - Direct (Childers)

687

1 you -- in the label, in the Pradaxa label as to how you can  
2 measure precisely the amount of Pradaxa that a bleeding  
3 patient has when they come in?

4 A. No.

5 Q. Without Boehringer providing that information to you,  
6 is there any way for us to know exactly how much Pradaxa  
7 Betty had in her blood when she had this GI bleed?

8 A. No.

9 Q. Were you aware that Boehringer tells doctors like you  
10 in Europe exactly how to measure Pradaxa blood levels?

11 A. I believe they have more information in Europe than  
12 they do in the United States.

13 Q. Is that the kind of information that you would believe  
14 would be helpful to you in treating patients here in West  
15 Virginia?

16 A. Definitely.

17 Q. And how would that help you?

18 A. Well, it would help me identify who is at higher risk  
19 of bleeding, whose level is too high because of these risk  
20 factors. So I may tell them to reduce the dose or not take  
21 the medicine or find another drug to use.

22 Q. Some drugs aren't right for everybody. Is that fair to  
23 say?

24 A. That's correct.

25 Q. You mentioned that, that Betty had what you call a

1 life-threatening GI bleed; is that right?

2 A. That's right.

3 Q. Are there different ways you categorize them as a  
4 doctor who treats GI bleeds as far as how bad they are?

5 A. Yeah. Well, you get the patient who comes in walking  
6 and talking to the office and has passed some blood through  
7 the rectum. They have normal vital signs and normal  
8 hemoglobin. So that's minor.

9 A major GI bleed would be when they bleed probably a  
10 couple units of blood. They may have rapid heart rate so  
11 they are a little bit hypertensive, but they do not  
12 necessarily need a blood transfusion. They may or may not.  
13 But usually it is less than four units, maybe one or two  
14 units.

15 We call that a major GI bleed because we see a drop in  
16 hemoglobin, typically one to two grams, maybe with a little  
17 bit of low blood pressure. So these are some of the  
18 criteria.

19 And then the life-threatening one is the one we talked  
20 about when you need four units of blood or more. Usually  
21 you have low blood pressure. You may have changes in mental  
22 status. An elderly person may be confused.

23 And in addition, you know, a hemoglobin drop of more  
24 than five grams, that's life-threatening.

25 Q. Okay. You reviewed the Pradaxa labels, right, the

Hazem Ashhab - Direct (Childers)

689

1 physician label in this case?

2 A. Yes.

3 Q. And, in fact, more than one as they changed over time?

4 A. Yes.

5 Q. If you could look in the binder you have in front of  
6 you, the first exhibit, which is Number 86.

7 If you could call up the third page of Exhibit 86.

8 MR. CHILDERS: Your Honor, I believe this is  
9 already admitted.

10 THE COURT: I'm sorry?

11 MR. CHILDERS: This is an already admitted  
12 exhibit. I apologize, Your Honor.

13 THE COURT: Right.

14 MR. CHILDERS: Okay.

15 BY MR. CHILDERS:

16 Q. Do you see on Page 3, Section 6.1 that talks about  
17 clinical trial experience?

18 Would you call up that middle paragraph just above  
19 Table 2. It's just called the "bleeding" paragraph. Okay.

20 Do you see it here that -- I'm going to ask you  
21 questions while she gets that ready.

22 Do you see in here that this is talking about the RE-LY  
23 study that was the pivotal clinical trial for getting  
24 Pradaxa approved for atrial fibrillation patients?

25 A. Yes.

1 Q. Do you see that? And in here do you see that they say,  
2 "This is how we define in the RE-LY study if someone had a  
3 major bleed or a life-threatening bleed." Do you see that?

4 A. Yes.

5 Q. And there about midway through the paragraph do you see  
6 where it says, "A life-threatening bleed met one or more of  
7 the following criteria"?

8 A. Yes.

9 Q. Do you see that?

10 A. Yes.

11 Q. And the third item in there is reduction in hemoglobin  
12 of at least five grams per deciliter. Do you see that?

13 A. Yes.

14 Q. Did Betty have that?

15 A. Yes.

16 Q. Okay. And the second one is transfusion of at least  
17 four units of blood. Do you see that?

18 A. Yes.

19 Q. And did Betty have at least four units of blood  
20 transfused?

21 A. Yes.

22 Q. So she met two of the criteria, not just one, for a  
23 life-threatening bleed if she had been in the RE-LY trial;  
24 right?

25 A. And I would argue on a third one too.

1 Q. Okay.

2 A. It depends on how you look at it. Necessitating  
3 surgical intervention, which she had colonoscopy and  
4 clipping.

5 Q. Okay.

6 A. Before the area of colonoscopy and clipping, she would  
7 go to surgery to have that part of the colon removed. So it  
8 depends on how you look at it, but that's another fact.

9 Q. All right. And so not only in your experience it's a  
10 life-threatening bleed, the company actually says that as  
11 well as how they define it in the RE-LY trial?

12 A. That's true.

13 Q. Okay. All right. I want to talk to you about -- go  
14 back to the actual hospitalization in May of 2013. And if  
15 we could look again on Page 32 which was the Discharge  
16 Summary we were looking at just a few minutes ago. Okay?

17 A. Okay.

18 Q. Do you see there it says at the bottom, "Patient was  
19 admitted and given two units of blood for a hemoglobin of  
20 6"?

21 A. Yes.

22 Q. Okay. Can you, can you tell the jury, what is a  
23 hemoglobin of 6? What does that mean to you?

24 A. Well, that's a very low hemoglobin. The hemoglobin is  
25 the major protein in your blood that carries the oxygen to

1 the vital organs. So if you want your lungs to have oxygen,  
2 your brain to have oxygen, your heart, your kidneys, you  
3 need normal hemoglobin or a hemoglobin within one to  
4 two grams of the normal.

5 Once you get to very low levels of hemoglobin, then you  
6 don't have the vehicle to deliver oxygen to your tissues,  
7 mainly the vital organs. And the brain is one of the most  
8 important organs and the kidneys as well. They are very  
9 sensitive to hypoxemia, meaning low oxygen in the blood.

10 Q. Okay. And what's a normal hemoglobin in a patient?

11 A. It can vary a little bit in the population in the test,  
12 the lab that does it, but females usually 12 to 14 and males  
13 14 to 16. So --

14 Q. So this is half of what you would expect it to be?

15 A. I would say so.

16 Q. And, and what does that mean to you when you see that?

17 A. So you have somebody who's really in a life-threatening  
18 situation where they don't have enough means to deliver  
19 oxygen to the vital organs. So these people would be at  
20 high risk for, you know, ischemic stroke, an insult to the  
21 heart, insult to the kidneys with this level of hemoglobin.

22 Q. Okay. And then we go on and see here it says she was  
23 evaluated by GI who took her for upper and lower  
24 endoscopies. An AVM of the colon was actively bleeding  
25 which was clipped. Do you see that?

1 A. Yes.

2 Q. Are those the procedures that you perform as well in  
3 your practice?

4 A. Yes.

5 Q. Okay. Could you tell the jury what, what is an AVM?

6 A. It stands for arteriovenous malformation which is  
7 basically an abnormal tiny vessel in the wall of the colon  
8 or the intestine that can easily bleed upon the blood being  
9 too thin or on friction or trauma.

10 So instead of having the normal vessels that taper down  
11 into the capillaries and meet together to transport from  
12 artery to vein, they actually make a little pooling of these  
13 capillaries. And that pooling of these little tiny vessels,  
14 because it's very thin and abnormal, is high risk for  
15 bleeding.

16 Q. Have you treated patients who have AVMs that don't  
17 bleed?

18 A. Yes.

19 Q. Do most AVMs bleed or not bleed?

20 A. No, most of them do not bleed.

21 Q. Okay. When is it that you most often see a bleeding  
22 AVM?

23 A. When people are taking what we call a blood thinner.  
24 Usually it's an anticoagulation medication that makes the  
25 blood too thin.

1 Q. Okay. If we could go on in this report, again do you  
2 see it says, "Her hemoglobin improved with two units of  
3 blood. She was given another two units for a total of four  
4 units." Do you see that?

5 A. Yes.

6 Q. Okay. And is that an unusual amount of blood to have  
7 to transfuse for a patient, four units?

8 A. It's a lot, but for somebody with a hemoglobin of 6,  
9 that's what you need.

10 Q. Okay. And then it says her hemoglobin went up to 10.8.  
11 Is there anything about Betty's physical condition that  
12 would make you think that that is probably a normal range  
13 for her to have a hemoglobin?

14 A. I would say, you know, 10 to 11 is okay for her because  
15 she has chronic kidney disease. So people with chronic  
16 renal failure usually tend to have a little bit lower  
17 hemoglobin and their body adjusts to that.

18 Q. And that baseline becomes just a little bit lower?

19 A. Yes.

20 Q. Okay. Betty was taking some other medications at the  
21 same time she had this bleed besides Pradaxa; correct?

22 A. Correct.

23 Q. Do you believe any of the other medications that she  
24 was taking played any part in the bleed?

25 A. She's on -- she was on two anti-platelet agents. I

1 recall aspirin and Plavix.

2 Q. What's the difference between an anti-platelet agent  
3 and an anticoagulant drug?

4 A. Okay. So the anti-platelet will inhibit the platelets  
5 that are usually running in your system from making an  
6 aggregate or a clot that will block an artery while the  
7 anticoagulants make your blood in general very thin.

8 Q. And how does that affect -- if someone is having a  
9 bleed or has damaged tissue, how do those two work together?

10 A. So the, the aspirin and Plavix will, will make you more  
11 likely maybe to ooze a little bit of blood. It's kind of  
12 like a faucet dripping water.

13 But the blood thinners may make you just having an open  
14 hose. Because the blood is too thin when it bleeds, it  
15 doesn't stop.

16 So you get one trickling faucet and one that's got an  
17 open faucet. The anticoagulants is the open faucet where  
18 the blood is too thin, and when it bleeds it doesn't stop.  
19 And the aspirin and Plavix is like the trickle.

20 Q. Okay. What role do you believe the Plavix and aspirin,  
21 if any, played in the bleed that Betty had?

22 A. Well, they're probably a contributing factor.

23 Q. Okay. You, you mentioned earlier you thought Pradaxa  
24 was the most substantial factor. How would you rate the  
25 Plavix and aspirin as opposed to Plavix as being likely

1 causes of the bleed?

2 A. Well, in our experience in gastroenterology, two things  
3 we, we notice in our practice; number one, the location of  
4 the bleeding and, number two, the amount of bleeding.

5 So with aspirin and Plavix you are more likely to see  
6 bleeding from upper gastro-intestine, let's say the stomach  
7 and maybe the duodenum, while with anticoagulants,  
8 especially Pradaxa, you are more likely to see the bleeding  
9 coming from the lower GI tract, mainly the colon.

10 Q. And where was Betty's bleed?

11 A. It was in the colon.

12 Q. Okay. The lower GI?

13 A. Lower GI. And then the second point is usually with  
14 aspirin and Plavix, you may bleed as an ooze, a little bit  
15 at a time, and it takes you a long time before your  
16 hemoglobin drops, while when you bleed -- if you have a  
17 lesion and it bleeds with anticoagulants, and Pradaxa is one  
18 of the higher risks for that, the bleeding is massive. They  
19 come in passing clots, a lot of blood.

20 So the amount of bleeding is more with anticoagulants  
21 and the location is lower GI and colon.

22 Q. If you had a patient who's at high risk of bleed, they  
23 come to you and, you know, you say this patient is at high  
24 risk of bleed and they're on all three of those medications  
25 and you want to take them off just one of them because

Hazem Ashhab - Direct (Childers)

697

1 you're worried about the bleed, which one are you going to  
2 take them off of - Pradaxa, Plavix or aspirin?

3 A. Now, from the gastrointestinal point of view, I  
4 probably would have them stop the Pradaxa or look for an  
5 alternative. Now, that's from my department, my part.

6 Now, there are other reasons for the other medications  
7 and their cardiologist usually is to make the call.

8 Q. Well, let's, let's look, if we could, if you look on  
9 Page 37 of the binder in front of you.

10 And if you could call that up.

11 This is a consult with Dr. Linsenmeyer. Do you see  
12 that?

13 A. Yes.

14 Q. And it was after Betty had had her bleed. It was about  
15 a month after she got out of the hospital. Do you see that?

16 A. Uh-huh.

17 Q. Okay. And he mentions here in the first paragraph  
18 that -- toward the bottom --

19 If you could call that up.

20 Do you see that he mentions that she had been in the  
21 hospital with new onset GI bleeding? Do you see that in the  
22 first paragraph of the history of present illness?

23 A. Yes.

24 Q. Okay. And it goes on to say that she had this AV  
25 malformation, had to stay in the hospital until June 8th,

1 and then went home. Do you see that?

2 A. Yes.

3 Q. Okay. If we could turn to the -- three pages in. It's  
4 Page 3 of three, 39 at the top. And I want to direct you  
5 down to the "Plan" section. Do you see that?

6 A. The "Plan," yes.

7 Q. Yes, sir. And this is -- Dr. Linsenmeyer is a  
8 cardiologist. Are you aware of that?

9 A. Yes.

10 Q. And do you see he says he would not anticoagulate her  
11 with recent gastrointestinal bleed. Do you see that?

12 A. Yes.

13 Q. And then he goes on a little bit farther down the  
14 last -- the second to last sentence he says, "We will resume  
15 Plavix in the event she needs cardiac catheterization and  
16 hold Pradaxa." Do you see that?

17 A. Yes.

18 Q. Is that consistent with what you just told us about  
19 which of these drugs you would be most afraid of causing a  
20 bleed for this patient?

21 A. Yes. In her case I would stop the Pradaxa as the --

22 Q. And that looks like what Dr. Linsenmeyer was saying as  
23 well; right?

24 A. Yes.

25 Q. Okay. Have you treated patients who are on warfarin,

1 Coumadin --

2 A. Yes.

3 Q. -- who have GI bleeds?

4 A. Yes.

5 Q. Okay. In your experience when those patients have a GI  
6 bleed, what do you normally find as far as their INR number?

7 Is it normal? Is it elevated?

8 A. Usually very high.

9 Q. Okay. And when you say very high, what do you mean?

10 A. Probably about -- above 10.

11 Q. Okay. How often do you see GI bleeding in a warfarin  
12 patient who has -- who's in therapeutic range, who's in  
13 between that two and three number?

14 A. It's not common as a known agent.

15 Q. It's possible; right?

16 A. Yes, but it's not common.

17 Q. Okay. Do you believe that Betty would have had a  
18 severe GI bleed in May of 2013 if she had still been on  
19 warfarin or Coumadin instead of Pradaxa?

20 A. I would think not, not a life-threatening bleed because  
21 she's been on Coumadin before and it was therapeutic and  
22 supratherapeutic, but she never had the life-threatening  
23 bleed before on Coumadin.

24 Q. Is there anything about Pradaxa -- is it -- do you know  
25 whether or not Pradaxa is more likely to cause a GI bleed

Hazem Ashhab - Direct (Childers)

700

1 than Coumadin?

2 A. We do.

3 Q. What, what do you know about that?

4 A. Well, from our experience, it's more than double. I  
5 mean, it's significantly higher than warfarin to cause GI  
6 bleeding, Pradaxa is.

7 Q. Okay. You mentioned that Betty did not have a  
8 life-threatening bleed while she was on Coumadin.

9 A. She didn't.

10 Q. All right. I want to talk about that because the  
11 jury's sort of heard mixed signals on that. I want to clear  
12 that up. Okay?

13 A. Okay.

14 Q. First of all, Betty had -- we already talked about  
15 this. She had chronic kidney disease; right?

16 A. Correct.

17 Q. And you told us that affects her hemoglobin and you  
18 would expect it to be a little lower than normal anyway?

19 A. Correct.

20 Q. What the jury has heard is that Betty -- Betty had to  
21 be taken off Coumadin at some point and it was potentially  
22 because of a GI bleed. Okay?

23 I want to show you records from November of 2008 where  
24 Betty was actually taken off the warfarin. Okay?

25 If you look in your binder at the very beginning of

Hazem Ashhab - Direct (Childers)

01

1 this same Section 2000-A, do you see that? Go to the first  
2 page. It's got the sticker on it. Do you see this is  
3 another History and Physical? This one is from November  
4 13th, 2008.

5 A. Correct.

6 Q. Okay. I want you to look at this H & P, the history of  
7 present illness, and tell me is there any mention of a bleed  
8 in there?

9 A. I don't see any.

10 Q. Okay. Why don't we turn the page, if you would, with  
11 me. And there is a section called "Review of Symptoms."

12 A. Yes.

13 Q. Okay. And what's a Review of Symptoms? Could you tell  
14 the jury what that section means?

15 A. That after you complete the main reason the patient  
16 came to the hospital and you get the detailed story of that,  
17 then particularly in elderly people with multiple medical  
18 problems, you go on a system by system asking them about  
19 their neurological function, their breathing, their heart,  
20 their intestines, their genitourinary tract, and their  
21 musculoskeletal.

22 So you're reviewing each and every system to make sure  
23 that you covered everything and you did not miss anything  
24 in, in what the patient told you. So it's basically a  
25 review of each and every system in your body.

1 Q. Do you see here that the GI is listed as a separate  
2 system?

3 A. Yes.

4 Q. What does it say next to GI?

5 A. "No melena, hematochezia, nausea, vomiting, or  
6 diarrhea."

7 Q. Can you tell the jury --

8 A. "She has chronic constipation and reflux."

9 Q. Sorry. I didn't mean to interrupt you. Can you tell  
10 the jury, what is melena?

11 A. Melena is transported blood that usually appears dark  
12 in color, almost black, because it's blood that has, that  
13 has passed through your gastrointestinal tract. So it gets  
14 partially digested by certain enzymes. So the blood changes  
15 color from bright red to dark. We call it melena. It's a  
16 reflection of GI blood loss basically.

17 Q. So when it says no melena, what does that mean to you?

18 A. That she did not have symptoms of passing blood at  
19 rectum or passing blood that she could see.

20 Q. And the next one is that she didn't have hematochezia;  
21 is that right?

22 A. Hematochezia is when you pass blood through the rectum.

23 Q. So if it says no hematochezia, what does that tell you?

24 A. There was no bleeding that she could see.

25 Q. Okay. And then if we could turn two more pages, you

Hazem Ashhab - Direct (Childers)

703

1 see -- and this would be Page 4 at the top. Do you see that  
2 this is a consult a couple of days later by Dr. Haberman?

3 A. Yes.

4 Q. And you understand him to be a cardiologist as well?

5 A. Yes.

6 Q. Okay. And do you see -- in this history of present  
7 illness do you see anything that says she's having a bleed?

8 A. I, I don't see.

9 Q. Okay.

10 A. If you can point it out to me, but I don't see any.

11 Q. Okay. And then if we look on the next page, there's a  
12 section called "Impression." Do you see that down toward  
13 the bottom?

14 A. Yes.

15 Q. Okay. And, actually, can you pull up the paragraph  
16 above it as well?

17 Just above "Impression" do you see the very last  
18 sentence in the diagnostic data it says the INR is  
19 therapeutic at 3.3? Do you see that just above the  
20 Impression, the word "Impression"?

21 A. Yes.

22 Q. What does that mean that the INR is therapeutic?

23 A. The INR is a lab test we use to monitor the degree of  
24 anticoagulation when a patient is on Coumadin. And we look  
25 at studies that tell you where your INR level should be.

1        So, for example, if somebody has atrial fibrillation  
2        like Mrs. Knight and you want to prevent a stroke, typically  
3        you like it to be between 2.5 to 3 or 2.5 to 3.5, in that  
4        range.

5        And if somebody has a heart valve, the numbers may be a  
6        little bit different. But we use that blood test to tell us  
7        how thin the person's blood is and to adjust their Coumadin  
8        dose.

9        Q. When you see in a medical record it says that the INR  
10       was therapeutic, what does that tell you as a doctor?

11       A. I'm assured that the patient is taking the proper dose  
12       of the medication.

13       Q. Okay. She's not over-anticoagulated? Is that fair to  
14       say?

15       A. No. It's therapeutic, so it's where she should be.

16       Q. Okay. And then if we look under "Impression," do you  
17       see Number 3 says anemia which might be secondary to the  
18       recent initiation of Coumadin. Do you see that?

19       A. Yes.

20       Q. Does it say anything in this Impression about a bleed,  
21       a GI bleed?

22       A. It does not.

23       Q. And then under "Recommendations," the first thing is  
24       they're going to stop the Coumadin. Do you see that?

25       A. Yes.

1 Q. If we could just go to the next page, yes, the  
2 following Page 6, there's the, the fifth recommendation.

3 Do you see that it says, "I'm hopeful that the  
4 transfusion will help with the heart rate which may be a  
5 response to anemia"?

6 Do you see that?

7 A. Yes.

8 Q. What does that mean to you?

9 A. That she was having tachycardia and he thought that the  
10 tachycardia, the rapid heart rate was because she had low  
11 hemoglobin, did not have enough blood. So he said if we  
12 give her blood, maybe that will help heart rate slow down a  
13 little bit and be close to normal.

14 Q. Okay, all right. I want to move on to the next page  
15 which is the following, the following day. Do you see that  
16 this is a consultation from Dr. Rohrbach?

17 A. Yes.

18 THE COURT: Excuse me.

19 Doctor, could you pull the microphone down just a  
20 little? When you look down at the medical record, it's not  
21 picking you up. Thank you.

22 BY MR. CHILDERS:

23 Q. Do you see this is a consultation from Dr. Rohrbach?

24 A. Yes.

25 Q. And if we go to the Impression on the next page, he

Hazem Ashhab - Direct (Childers)

06

1 says, "Anemia. This certainly does need to be evaluated  
2 given her long-term need for anticoagulation. We'll start  
3 her workup with an upper endoscopy. And if this is  
4 unremarkable, at some point she probably will require a  
5 colonoscopy as well."

6 Do you see that?

7 A. Yes.

8 Q. And could you tell the jury what an endoscopy is?

9 A. Endoscopy is the test by which we take a flexible tube  
10 with a camera at the end and go in the mouth down the food  
11 tube, the esophagus into the stomach.

12 We pass the stomach into the first part of the small  
13 intestine called the duodenum looking for abnormal lesions  
14 like a bleeding source, ulcer, or cancer or a stricture.

15 Colonoscopy is when you take a different tube, longer  
16 usually, with a camera at the tip and you go through the  
17 rectum into the entire large intestine, and then where the  
18 junction between the small intestine and the colon is.

19 Again, the colonoscopy is designed to look for abnormal  
20 lesions in the colon like colon polyps and colon cancer, AV  
21 malformations, bleeding source, inflammation,  
22 diverticulosis, all that.

23 Both tests have, have abilities for diagnosis as well  
24 as a therapeutic option; for example, to remove polyps to  
25 prevent cancer or to clip a lesion and stop bleeding. So

1 they are used as diagnostic and therapeutic tools.

2 Q. Okay. And if we turn three pages in this record to  
3 Page 11, do you see where that upper endoscopy was actually  
4 performed two days later?

5 A. Yes.

6 Q. And what was the -- did they find any blood, first of  
7 all? Do you see the part right in the middle that says "no  
8 blood was noted"?

9 A. Yeah. It says "normal upper endoscopy."

10 Q. What does that mean if it's a normal endoscopy?

11 A. That they found no lesions to report.

12 Q. Okay.

13 A. No bleeding, no ulcers, nothing to report.

14 Q. And then I want you to flip back two pages. And do you  
15 see that there was a cardiac catheterization that was  
16 performed the day before that?

17 A. Yes.

18 Q. Is that an invasive procedure?

19 A. Cardiac catheterization, yes.

20 Q. Is that a procedure where you would have a patient stop  
21 taking their anticoagulant before you performed it?

22 A. Yes.

23 Q. Okay. And so in this particular case, she's off  
24 Coumadin and they perform a catheterization and put in  
25 stents; correct?

Hazem Ashhab - Direct (Childers)

708

1 A. Yes.

2 Q. Okay. And then I want you to look at "Plan" on the  
3 very, the next page, Page 10, the very last one, Number 6 in  
4 "Plan." Can you see it says, "The decision of whether to  
5 restart the Coumadin will be left to Dr. Haberman."

6 Do you see that?

7 A. Yes.

8 Q. So you have to stop Coumadin before you have a cardiac  
9 catheterization like she had; correct?

10 A. Yes.

11 Q. And then this doctor, in particular Dr. Gunnalaugsson,  
12 is saying, "I'm going to leave that up to another doctor to  
13 decide whether or not to put her back on the Coumadin."  
14 Right?

15 A. Yes.

16 Q. Then I want you to turn to Page 12 in this record which  
17 is the Discharge Summary. Do you see that?

18 A. Yes.

19 Q. You told us what a Discharge Summary is. So I want, I  
20 want to ask you, do you see anything -- and there are 24  
21 items listed on her Discharge Diagnosis; correct?

22 A. Yes.

23 Q. Is any one of those GI bleed?

24 A. No.

25 Q. Okay. The jury also heard that -- has heard that Betty

Hazem Ashhab - Direct (Childers)

709

1 got a clot in her arm after she stopped the Coumadin in  
2 November of 2008, that she got a clot in her arm in February  
3 of 2009. Do you recall from the medical records seeing that  
4 that occurred?

5 A. Yes.

6 Q. All right. I want to direct you to another record,  
7 Page 52 of this particular set we're looking at now. Let me  
8 know when you're there.

9 A. 52?

10 Q. Yes, sir.

11 A. Yes.

12 Q. Do you see this is a consultation from a Dr. Baryun on  
13 February 10, 2009?

14 A. Yes.

15 Q. So just a few months after the record we just saw;  
16 correct?

17 A. Yes.

18 Q. And the reason for the consultation is bradycardia;  
19 right?

20 A. Yes.

21 Q. And then if we look under "History of Present Illness"  
22 about midway down, do you see it says, "Patient has been on  
23 Coumadin in the past. However, it was held because of the  
24 percutaneous coronary intervention and was not restarted."  
25 Do you see that?

Hazem Ashhab - Direct (Childers)

10

1 A. Yes.

2 Q. Is that percutaneous coronary intervention the cardiac  
3 catheterization we just looked at?

4 A. Yes.

5 Q. Does it say anything in this record about her having a  
6 bleed, whether it was acute or chronic, and that's the  
7 reason why Coumadin was stopped?

8 A. It does not. It says it was stopped because of the  
9 PTC, the percutaneous intervention with the catheterization.

10 Q. I want you to turn now to -- sorry. I'm making you  
11 skip around here. If you go to Page 23 of this same set of  
12 records, you should find another consultation that was three  
13 days after that, February 13th, 2009. Do you see that?

14 A. Yes.

15 Q. And at this point, Betty's not on Coumadin; right?

16 A. Correct.

17 Q. She had been taken off of it. And do you see what it  
18 says under his "History of Present Illness," the first  
19 sentence? Do you see it says, "The patient is a 79-year-old  
20 white female seen in consultation at the request of Dr. Dawn  
21 MacFarland for evaluation of anemia." Right?

22 A. Yes.

23 Q. Anemia, you told us, is where the hemoglobin is a  
24 little low and you want to find -- try to find out why;  
25 correct?

Hazem Ashhab - Direct (Childers)

11

1 A. Yes.

2 Q. At least that's what they're doing here. And at this  
3 point if you look under "Medications," there are 15 things  
4 listed, not one of which is Coumadin or warfarin.

5 A. Yes.

6 Q. Okay. And then if we turn to the next page, do you see  
7 a section that's called "Diagnostic Data"?

8 A. Yes.

9 Q. And under that do you see that she had labs checked and  
10 that her hemoglobin had dropped to 9.1? Do you see that?

11 A. Yes.

12 Q. That's pretty -- almost exactly what it was in November  
13 of 2008 when they took her off Coumadin; correct?

14 A. Yes.

15 Q. Okay. But at this point, she's not on Coumadin; right?

16 A. Right.

17 Q. And she's diagnosed with anemia; right?

18 A. Yes.

19 Q. Okay, all right. I want to get into now, if we could,  
20 the Pradaxa label that was in effect when Betty Knight was  
21 started on Pradaxa. Did you review that label?

22 A. Yes.

23 Q. Okay. And the jury saw this morning that the label  
24 that Dr. MacFarland had available to her was Exhibit Number  
25 86 in your binder, the label that was revised in March of

1 2011, if you would turn to that with me.

2 Do you see on the front page, the very first page  
3 what's called the "Highlights of Prescribing Information"?

4 A. Yes.

5 Q. And at the -- and in the very right column, the top  
6 half, is there a section there called "Drug Interactions"?  
7 Do you see a section called that?

8 A. No.

9 Q. Do you see anything in this "Highlights of Prescribing  
10 Information" that tells a physician that a patient who has  
11 severe renal impairment and is taking a P-gp inhibitor  
12 should not get Pradaxa?

13 A. No.

14 Q. Okay. I want you to turn to the third page. And at  
15 the bottom there's a section called "Drug Interactions." Do  
16 you see that?

17 A. Yes.

18 Q. And when you look at that section, is there anything  
19 there that tells a physician that a patient with severe  
20 renal impairment who's taking a P-gp inhibitor should not  
21 take Pradaxa?

22 A. No.

23 Q. Okay. You told us earlier Coreg is a P-gp inhibitor;  
24 right?

25 A. Yes.

Hazem Ashhab - Direct (Childers)

13

1 Q. And it's a drug that is commonly taken by patients who  
2 have AFib; correct?

3 A. Yes.

4 Q. Was Betty taking that drug when she started Pradaxa?

5 A. Yes.

6 Q. I want you to look back on Page 2 there is a section  
7 5.3 at the very bottom of this label. And you see it's  
8 called "Effect of P-gp inducers inhibitors on dabigatran  
9 exposure." Do you see that?

10 A. Yes.

11 Q. Okay. And that's what we're talking about. Coreg is a  
12 P-gp inhibitor; right?

13 A. Yes.

14 Q. Is the word "Coreg" or the chemical name "Carvedilol,"  
15 are either of those in this label at all?

16 A. No.

17 Q. All right. I want to turn now to a change that was  
18 made in the label after Betty started taking Pradaxa. Okay?

19 If we could look at Exhibit 88 which is the label as it  
20 was revised in January, 2012. Betty is already on Pradaxa.  
21 The decision had already been made to put her on it. Do you  
22 see that?

23 A. Yes.

24 Q. Now, when we look at this section in the "Highlights of  
25 Prescribing Information --"

Hazem Ashhab - Direct (Childers)

14

1 I'm sorry. Let's take that down.

2 MR. CHILDERS: I apologize, Your Honor. I thought  
3 that was already in evidence. I would move Exhibit 88 into  
4 evidence.

5 THE COURT: Any objection?

6 MR. LEWIS: No objection, Your Honor.

7 THE COURT: It's admitted and may be published.

8 MR. CHILDERS: Thank you, Your Honor.

9 (Plaintiffs' Exhibit Number 88 admitted into evidence.)

10 BY MR. CHILDERS:

11 Q. And that particular label -- if we could put it back up  
12 -- sometimes I get a little ahead of myself. Sorry.

13 Do you see now there's a section that's been added  
14 called "Drug Interactions"?

15 A. Yes.

16 Q. Okay. And the third item in that section says, "P-gp  
17 inhibitors in patients with severe renal impairment Pradaxa  
18 use is not recommended."

19 Do you see that?

20 A. Yes.

21 Q. Then if we turn to Section 5.3 which is on the third  
22 page of the label -- if we could blow up 5.3, that whole  
23 section. Okay.

24 Do you see the little line along the edge? It's a  
25 straight line going down next to the second two paragraphs

1 in this section. Do you see there's a little line there  
2 next to it?

3 A. Yes.

4 Q. Okay. That information was not -- the part that's in  
5 this, these two paragraphs was not in the label we just  
6 looked at from when Betty started taking Pradaxa; correct?

7 A. That's correct.

8 Q. And then at the very last sentence, again it says,  
9 "Avoid use of Pradaxa and P-gp inhibitors in patients with  
10 severe renal impairment." Correct?

11 A. Yes.

12 Q. It doesn't say avoid certain P-gp inhibitors in  
13 Pradaxa. It's just P-gp inhibitors in general. Correct?

14 A. Yes.

15 Q. Okay. I want to take you to one more part in here, the  
16 very next page. There's a drug interaction section again.  
17 Do you see that?

18 A. On Page 4 you said?

19 Q. Yes, sir, the very next page, Page 4.

20 A. Yes.

21 Q. And here at the very bottom do you see the sentence  
22 that says, "The concomitant use of Pradaxa and P-gp  
23 inhibitors in patients with severe renal impairment should  
24 be avoided."

25 Do you see that? It's the last, the last sentence in

1 that section of Drug Interaction.

2 A. Page 4?

3 Q. I'm sorry, Page 4, Section 7.

4 A. Section 7. Yes, I see that. Yes, that's correct.

5 Q. These changes that we just looked at in this label, as  
6 a doctor would you consider those to be significant changes  
7 to the label?

8 A. Yes, very much so.

9 Q. And as a doctor, what would you expect the drug company  
10 to do when they make significant changes like this to a drug  
11 label?

12 A. They contact the doctors, the pharmacists, and -- the  
13 pharmacies and sometimes even the patients.

14 Q. And how do they do that? Do they send letters? Do  
15 they call them? What do they do?

16 A. They send a letter with a big label on it that says  
17 "Warning" in red. And, and they mention these changes and  
18 they usually are highlighted.

19 And then often we get calls from the pharmacy saying  
20 that we got an update on this medication by the manufacturer  
21 and your patient is taking this and this medication and I  
22 think they shouldn't be together, so you have to choose  
23 between the two. So we get it in more than one way.

24 Q. And in this particular case having reviewed the  
25 evidence about what happened with Ms. Knight, do you know --

Hazem Ashhab - Direct (Childers)

17

1 the company never sent a letter like that to Dr. MacFarland;  
2 correct?

3 A. To my knowledge, they did not.

4 Q. One more section I want to look at here with you on  
5 Page 2 of this document. It's called "Dosing Adjustments."  
6 Do you see that?

7 A. Yes.

8 Q. And, again, it's got a little line there saying they've  
9 made some changes here. Do you see that? The line that  
10 goes along the side of it on the left-hand side?

11 A. Yes.

12 Q. Okay. This tells the doctor what dose you should give  
13 to your patient; right?

14 A. Yes.

15 Q. Does it say anything in here in this dosing section to  
16 tell a doctor, "Don't give Pradaxa to a patient with severe  
17 renal impairment if they're already taking a P-gp  
18 inhibitor"?

19 A. No, it does not.

20 Q. Do you recall reading Dr. MacFarland's deposition in  
21 preparation for -- or in forming your opinions in this case?

22 A. Yes.

23 Q. And do you recall she was asked all kinds of questions  
24 about how difficult it was on occasion to keep Betty Knight  
25 in INR range?

Hazem Ashhab - Direct (Childers)

18

1 A. Yes.

2 Q. If Pradaxa is not an appropriate medication for  
3 anticoagulation for a patient, what difference does it make  
4 if you have to adjust their warfarin if they can't go on  
5 Pradaxa anyway?

6 A. Not much. It's a little inconvenience, but the patient  
7 will come to the doctor and have the INR done if need be.

8 Q. Okay. Based on what you see in the label as it was  
9 changed after Betty had already been started on the  
10 medication, would you agree that it's not an appropriate  
11 medicine for her?

12 A. It should have been stopped, no.

13 Q. And in order for the doctor to know that change has  
14 been made, the drug company has to take some affirmative  
15 action to tell them; correct?

16 A. That, that's correct.

17 Q. You get letters like that; right?

18 A. I do.

19 Q. Okay, all right. I want to talk to you now about what  
20 happened to Betty after she had the bleed. Okay?

21 A. Okay.

22 Q. If we could go back to this section 2000-A, go to the  
23 34th page. Let me know when you're there.

24 A. Page 34?

25 Q. Yes, sir. Do you see this is the Discharge Summary

Hazem Ashhab - Direct (Childers)

19

1 from June 8th when Betty got out of the skilled nursing  
2 portion of the hospital?

3 A. Yes.

4 Q. Okay. And the first diagnoses was the admitting  
5 diagnoses and the discharge diagnoses. It says, "General  
6 debility stemming from various medical problems including,"  
7 it says, "chronic anemia stemming from severe  
8 gastrointestinal blood loss due to an AV malformation."

9 Do you see that?

10 A. Yes.

11 Q. Do you recall from Dr. Abdelgaber's testimony he said  
12 that word actually should say "acute anemia?" Do you recall  
13 he said that?

14 A. Yes.

15 Q. And do you agree with that based on your review of the  
16 records?

17 A. Yes.

18 Q. Between the hospital and the skilled nursing center,  
19 Betty was in -- Betty was in their care at St. Mary's for  
20 about three weeks; right?

21 A. Correct.

22 Q. In your experience, is that an unusual amount of time  
23 for someone to have to be in a hospital for a GI bleed?

24 A. Yes, it's too long.

25 MR. LEWIS: Objection, Your Honor, leading.

Hazem Ashhab - Direct (Childers)

1 THE COURT: I'm sorry?

2 MR. LEWIS: He's doing a lot of leading here in  
3 the last few minutes.

4 THE COURT: He's an expert, but don't lead him  
5 about matters like that.

6 MR. CHILDERS: Sure. Sorry, Your Honor.

7 BY MR. CHILDERS:

8 Q. In your experience, how does three weeks in a hospital  
9 compare for a GI bleed patient?

10 A. Usually people with simple gastrointestinal bleed stay  
11 just for a couple of days. When the bleeding is  
12 life-threatening, it's expected they stay longer than a  
13 couple of days, maybe five to seven days.

14 But when people have a life-threatening condition and  
15 they also have co-morbidities, it may take them longer. But  
16 usually in this day and age a hospital stay more than a week  
17 is considered too long unless there are things going on or  
18 surgeries or other complications. But for a  
19 gastrointestinal bleed, staying in a hospital for two to  
20 three weeks is too long of a period.

21 Q. Where it says on that diagnoses that we just saw, it  
22 said "general debility." Do you recall it said that?

23 A. Yes.

24 Q. What does that mean as far as what was going on with  
25 Betty Knight at that time?

Hazem Ashhab - Direct (Childers)

21

1 A. At the time of discharge you mean or admission or --

2 Q. During that time where she was -- why does that --

3 okay. First of all, it's in the diagnoses. So my question  
4 to you is what does that mean so we can explain to the jury?

5 A. Well, you have someone with multiple medical problems,  
6 elderly person, and they get an insult on top of that and  
7 they de-condition. They will be performing in a certain  
8 baseline performance which is not great, but it's getting  
9 them from here to there to do their daily activities.

10 And then they go through a major insult, in this case a  
11 life-threatening bleeding, they de-condition from that level  
12 of just getting by or getting along and they are -- they  
13 cannot go back to that level. So we call them  
14 de-conditioned or debilitated.

15 That includes generalized weakness, not being able to  
16 perform daily functions, sometimes not able to take care of  
17 themselves.

18 Q. Okay. What was your understanding from this record  
19 what the cause of the general debility was for Betty Knight?

20 A. Multiple medical problems compounded by a  
21 life-threatening GI bleed.

22 Q. Did you review the records for Betty's treatment after  
23 the GI bleed up until the time she passed?

24 A. Yes.

25 Q. And I want to ask you about some of those. Okay?

1 A. Okay.

2 Q. If we could turn to Page 37 in the record. We've  
3 already looked at it once, but I want to talk to you about a  
4 different part of it. Okay?

5 A. Okay.

6 Q. This is the record from July 12th, 2013, Dr.  
7 Linsenmeyer. Do you see that?

8 A. Yes.

9 Q. If you look down under "History of Present Illness,"  
10 the second full paragraph --

11 A. Yes.

12 Q. -- do you see the first sentence? Could you read that  
13 to the jury?

14 A. "She has been weak since all of her recent admissions.  
15 She is just not bouncing back. She is having exertional  
16 shortness of breath."

17 Q. Okay. Let me stop you there. The statement she's just  
18 not bouncing back, what, what does that mean to you?

19 MR. LEWIS: Objection, Your Honor, foundation.  
20 That's not a medical term.

21 THE COURT: Sustained.

22 MR. CHILDERS: I'll withdraw the question, Your  
23 Honor.

24 BY MR. CHILDERS:

25 Q. Was that a common thing that you saw in these records

1 saying that she wasn't bouncing back after the bleed?

2 A. Yes. I believe it was mentioned on more than one  
3 occasion.

4 Q. Okay. Let's look, then, if we could on Page 40. Do  
5 you see this is a History and Physical from June 22nd, 2013?

6 A. Yes.

7 Q. What's the chief complaint?

8 A. She is not any better is her chief complaint.

9 Q. Is that consistent with the record we just saw?

10 A. Yes.

11 Q. Okay. And then if we turn Page 43, do you see this is  
12 a Discharge Summary from July 22nd, 2013?

13 A. Page 43?

14 Q. 43, yes, sir.

15 A. Yeah.

16 Q. Do you see that?

17 A. Yes.

18 Q. What's the first diagnosis?

19 A. Generalized debility and disuse myopathy.

20 Q. Okay. And you told us about debility a few minutes  
21 ago; right?

22 A. Yes.

23 Q. And then if we go under "Hospital Course," if we could  
24 blow that up, could you read for us what the first, the top  
25 line says?

1 A. Under "Hospital Course"?

2 Q. Yes.

3 A. "The patient came in because of multiple complaints.  
4 She is extremely weak. She is not getting better."

5 Q. Is that consistent with the two records that we just  
6 looked at?

7 A. Yes.

8 Q. Then if we turn to Page 45, do you see this is another  
9 Discharge Summary from August 17th, 2013?

10 A. Yes.

11 Q. And do you see under -- if we could blow up "Hospital  
12 Course" again.

13 Could you read for the jury, what's the first sentence  
14 that it says under "Hospital Course"?

15 A. "The patient was admitted to our skilled nursing unit  
16 due to just general debility."

17 Q. Is that consistent with the records that we have just  
18 talked about?

19 A. Yes, it is.

20 Q. Is that consistent with the Discharge Summary we saw  
21 from where she got out of the skilled nursing after the GI  
22 bleed?

23 A. Yes, it is.

24 Q. Then if we turn to Page 47, do you see this is a  
25 History and Physical from August 22nd, 2013?

1 A. Yes.

2 Q. Then if we could blow up "History of Present Illness."  
3 Could you just read the first sentence?

4 A. "The patient is an 84-year-old lady with multiple  
5 medical problems recently admitted with chest pain and  
6 generalized debility."

7 Q. And then what it does it say, the rest of that  
8 sentence?

9 A. "Was sent to the skilled nursing unit where she had  
10 some rehabilitation."

11 Q. Okay. And then I want to -- if we could blow up "Past  
12 Medical History" that's just underneath there.

13 A. Uh-huh.

14 Q. And this is more than two months after she got out of  
15 the hospital for the GI bleed; correct?

16 A. Yes.

17 Q. Okay. Number 15, could we call that out. What does  
18 that say?

19 A. "History of AV malformation and bleeding."

20 Q. Is that the bleeding from the May, 2013,  
21 hospitalization?

22 A. Yes.

23 Q. Then if we could turn to Page 50. Do you see this as a  
24 History and Physical from September 1st, 2013?

25 A. Yes.

Hazem Ashhab - Direct (Childers)

26

1 Q. And I want to blow up "History of Present Illness."

2 This is the day before she died; right?

3 A. Yes.

4 Q. And if we look at the first sentence, it starts out --

5 it says, "Weak and debilitated 84-year-old white female with

6 a long list of medical problems including," and it has quite

7 a few listed; correct?

8 A. Yes.

9 Q. And do you see five sentences down and they include in

10 this AV malformation with bleed of some sort? Do you see

11 that?

12 A. Yes.

13 Q. Okay. Did you review Dr. Abdelgaber's testimony in

14 this case?

15 A. Yes.

16 Q. Okay. Do you recall his testimony that from the time

17 Betty Knight suffered her GI bleed in May of 2013 that her

18 health declined and never really recovered like he hoped it

19 would? Do you remember him saying that?

20 A. Yes, I do.

21 Q. And do you remember him saying that multiple times

22 between the bleed and the time of her death she came back to

23 the hospital and was complaining each time that she just

24 wasn't getting better? Do you recall him saying that?

25 MR. LEWIS: Objection to leading again, Your

Hazem Ashhab - Direct (Childers)

27

1 Honor, walking evidence in the record.

2 THE COURT: Well, it is evidence in the record.

3 Try not to lead.

4 MR. CHILDERS: Yes, sir. I apologize. I didn't  
5 feel like I was leading, but I'll rephrase the question.

6 BY MR. CHILDERS:

7 Q. Do you remember Dr. Abdelgaber's testimony --

8 A. Yes.

9 Q. -- about what he thought of how Betty Knight did after  
10 she had the bleed?

11 A. Yes.

12 Q. And the jury has seen that as well.

13 A. Yes.

14 Q. Do you agree with Dr. Abdelgaber with what he said  
15 about Betty Knight's debility after the bleed up to the time  
16 of her death?

17 A. Yes, I do.

18 Q. Do you believe that Betty Knight's bleed in May of 2013  
19 contributed to her death in September of that same year?

20 A. Yes, I do.

21 Q. Could you explain to the jury why you think that, why  
22 you believe that?

23 A. Okay. So you get somebody, in this case Ms. Knight,  
24 with multiple medical problems. She has multi organs that  
25 do not function well. And she's just pivoting around the

1 edge.

2 And then you hit them with a life-threatening GI  
3 bleeding. You think they may not even survive from it.  
4 Well, she pulled through, but she never went back to where  
5 she was before because it was just too much of a hit on her.

6 Her hemoglobin dropped down to 6. She wasn't  
7 delivering enough oxygen to her vital organs. She became  
8 weak and debilitated. They did all that they could for her.  
9 They gave her blood. They sent her to rehab. They gave her  
10 medication. But she just did not bounce back to where she  
11 was before that major hit on the head, the major GI bleed.

12 It's life-threatening. It's a big hit. Some people  
13 even don't make it through the bleed itself. She was lucky  
14 to make it for a few months, but it was too big of a hit on  
15 somebody with all these risk factors at her age.

16 Q. And I just want to make sure the jury understands.  
17 What's your opinion on whether or not she would have had  
18 this GI bleed if she had been on warfarin and had not  
19 switched to Pradaxa?

20 A. I don't think she would have had it as bad. I mean,  
21 she's at high risk for bleeding but she was on Coumadin for  
22 years and the level was high but she never had the  
23 life-threatening bleed. So from that history on that  
24 particular patient, I would say "no."

25 Q. The opinions that you've given us today, have they all

Hazem Ashhab - Direct (Childers)

29

1 been to a reasonable degree of medical certainty?

2 A. I believe so.

3 MR. CHILDERS: That's all the questions I have.

4 THE COURT: All right. We're going to take about  
5 a ten-minute recess before the cross-examination. You may  
6 retire to the jury room.

7 Doctor, you can step down but don't discuss your  
8 testimony. Thank you.

9 (Recess taken at 3:07 p.m.)

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Hazem Ashhab - Cross (Lewis)

730

1 (Jury not present.)

2 THE COURT: All right. Are we ready to proceed?

3 Let's bring the jury out.

4 (Jury present.)

5 THE COURT: All right. Be seated.

6 Mr. Lewis, cross-examination?

7 MS. JONES: May it please the Court, Members of the  
8 Jury.

9 CROSS-EXAMINATION

10 BY MR. LEWIS:

11 Q. Dr. Ashhab, how are you, sir?

12 A. Good. Thank you.

13 Q. We've met outside in the hallway, but for the record, my  
14 name is John Lewis, and I have some questions for you this  
15 afternoon.

16 Doctor, for your convenience, I've set some of the  
17 documents that I may cover with you in front of you. I've  
18 also provided a copy to opposing counsel and the Court as  
19 well. Let me get a few kind of basics out of the way, if I  
20 may, Doctor.

21 Now, you are a gastroenterologist; is that correct?

22 A. Correct.

23 Q. All right. In so being a -- and may I say GI?

24 Is that a common --

25 A. Yes.

1 Q. -- abbreviation?

2 You probably don't like that.

3 A. No, it's fine.

4 Q. But in the context of being gastroenterologist, the GI,  
5 you did prescribe medication for some of your patients.

6 Is that fair to say?

7 A. Yes.

8 Q. What you don't do is ever prescribe Pradaxa or  
9 anticoagulant medication, correct?

10 A. Correct.

11 Q. Okay. But with respect to the medications that you do  
12 prescribe, you, before you do so, review the physician label  
13 for those medications.

14 Is that fair?

15 A. Correct.

16 Q. And you have a communication with your patient about the  
17 risks and benefits of that medication, correct?

18 A. Yes.

19 Q. And to the extent those medications come with a patient  
20 guide or a Medication Guide, you provide that to your  
21 patients, right?

22 A. Yes.

23 Q. But you don't leave the room and rely solely on the  
24 Medication Guide to provide risk and benefit information to  
25 your patients, do you?

1 A. No. I discuss it with them.

2 Q. You have a verbal discussion?

3 A. Yes.

4 Q. And as far as you know, that is the way doctors do it here  
5 in West Virginia, right?

6 A. Correct.

7 Q. This state is no different than any other in the United  
8 States when it comes to prescription medicines, is it?

9 A. That's true.

10 Q. All right. And when patients ask for the physician  
11 label -- I don't know how many of yours do, but when they do,  
12 you provide it to them, right?

13 A. Yes.

14 Q. Do some of your patients ask for the more technical  
15 information in the physician label to take a look at it before  
16 they take a medication?

17 A. Some of my patients will ask about resources. We are in  
18 the era of the Internet, so I point them to certain websites  
19 to get more information about it.

20 Q. All right. And to educate yourself about a medication  
21 before you prescribe it to a patient, you do a little bit of  
22 your own research, don't you, sir?

23 A. Yes.

24 Q. You not only rely on the physician label, but you may do  
25 additional research yourself, correct?

Hazem Ashhab - Cross (Lewis)

733

1 A. Sometimes I do.

2 Q. A good doctor is going look at literature or maybe talk to  
3 colleagues or something along those lines, fully educate  
4 yourself about the risks and benefits associated with a  
5 medication that you're going to prescribe.

6 Fair to say?

7 A. Yes, sir.

8 Q. All right. And that's what you do in your practice?

9 A. Yes.

10 Q. And you think that's a reasonable approach to educating  
11 patients about the risks and benefits of a medication?

12 A. I do.

13 Q. How many times in your career have you prescribed a  
14 medication solely because a patient came in and said they saw  
15 a TV ad and did no research on your own?

16 A. I do not do that usually.

17 Q. You would never do that, would you, Doctor?

18 A. I wouldn't.

19 Q. Right.

20 So even if a patient came to you and said, hey, I saw a TV  
21 ad, you would assess the risks and benefits for that patient  
22 independently on your own before prescribing that medication.

23 Fair to say?

24 A. Yes.

25 Q. All right. Let's move to a different subject, and that is

1 your treatment and diagnosis of what I'll call GI bleeds,  
2 gastrointestinal bleeds. Okay? And you talked a little bit  
3 about that in your direct examination.

4 If I recall correctly, you treat maybe a GI bleed once or  
5 twice or even more per week, right?

6 A. Yes.

7 Q. Okay. Fair to say it's a frequent occurrence in the  
8 United States in the patient population to have GI bleeds?

9 A. Yes.

10 Q. Okay. Doctors like yourself exist all over the United  
11 States treating those complications. Is that fair?

12 A. Correct.

13 Q. And you would agree with me that they're more prevalent in  
14 the elderly population?

15 A. Correct.

16 Q. All right. One type of -- and GI bleeds can occur -- you  
17 can have upper GI bleeds, you can have lower GI bleeds. They  
18 can occur anywhere in the GI system.

19 Fair to say?

20 A. Correct.

21 Q. In the lower GI system, those are often diagnosed with a  
22 colonoscopy; is that fair?

23 A. Correct.

24 Q. But you can also diagnose a lower GI bleed without doing a  
25 colonoscopy on occasion; is that right?

1 A. Yes.

2 Q. Okay. Perhaps a patient is too ill or not well enough to  
3 do a colonoscopy, so you have to look at other information or  
4 other detail to see if there is a GI bleed; is that right?

5 A. Yes.

6 Q. And you've done that on occasion, correct?

7 A. Sometimes.

8 Q. You would prefer to do a colonoscopy, is that right, to  
9 rule it in or rule it out?

10 A. Well, it's really more accurate and precise, and it gives  
11 you the option to do a therapeutic intervention. So I don't  
12 know what you are talking about in terms of other methods,  
13 but -- a bleeding scan is a common thing we use sometimes, but  
14 it gives you a road map. It doesn't give you exact location.

15 Q. Right.

16 Oftentimes during a colonoscopy, you can repair or treat  
17 the very source of the bleed or the injury; is that fair?

18 A. Yes. Correct.

19 Q. All right. You talked a little bit about AVM, antero --

20 A. Arteriovenous malformation.

21 Q. Arteriovenous malformation.

22 That is something that can occur in patients who are  
23 elderly. Is that fair to say?

24 A. Yes.

25 Q. Or not elderly; is that right?

1 A. Less common.

2 Q. Okay. You've treated folks for AVMs who have not been on  
3 anticoagulant medication; is that right?

4 A. Yes.

5 Q. Okay. And you've treated folks for AVMs that have been on  
6 anticoagulant medication, right?

7 A. Yes.

8 Q. And when I say anticoagulant medication, you've treated  
9 folks for GI bleeds, including AVMs, who have been on  
10 warfarin, right?

11 A. Yes.

12 Q. Okay. That can happen, right?

13 A. Yes.

14 Q. It's a risk of anticoagulant medication, correct?

15 A. Yes.

16 Q. You've treated patients who have been on Xarelto, right?

17 A. That's true.

18 Q. And Pradaxa?

19 A. Yes.

20 Q. And Plavix?

21 A. Uh-huh.

22 Q. Yes?

23 A. Yes.

24 Q. And Eliquis?

25 A. Yes.

Hazem Ashhab - Cross (Lewis)

737

1 Q. All right. Fair to say that no anticoagulant medication  
2 exists in the United States today that avoids entirely the  
3 risk of a GI bleed?

4 Is that fair to say?

5 A. I don't know of any.

6 Q. You're unaware of any sitting here today.

7 Okay. Let's talk about the treatment of a diagnosed GI  
8 bleed. If you're aware that a patient has a GI bleed, the  
9 first thing you want to do is make sure the patient is stable.

10 Is that fair?

11 A. Yes.

12 Q. And by stable, I mean not in a distress and not in a  
13 situation where their life is seriously and imminently in  
14 danger.

15 Fair to say?

16 A. Correct.

17 Q. Okay. Once that is done, then you start to figure out a  
18 plan of how to address the complication; is that correct?

19 A. Yes.

20 Q. And that could mean adjusting medication at least  
21 temporarily; is that right?

22 A. Yes.

23 Q. For someone on an anticoagulant medication, any of them --  
24 Xarelto, Eliquis, Pradaxa, warfarin -- you might stop the  
25 medication for a temporary period of time?

1 A. Yes.

2 Q. And that allows you to better treat the complication; is  
3 that fair?

4 A. Yes.

5 Q. All right. That's very common; is that right?

6 A. Yes.

7 Q. The next thing you may want to do, and probably do, is to  
8 identify the source of the injury or the complication; is that  
9 right?

10 A. Yes.

11 Q. And in the source of -- in the instance of an AVM, you  
12 want to identify where the AVM is and determine whether  
13 something can be done to repair or treat it.

14 Fair to say?

15 A. Yes.

16 Q. All right. And you would agree with me that, generally  
17 speaking, complications in the lower GI tract like AVMs are  
18 typically resolved within about a day, most of them?

19 A. If you do intervention, you mean? If you clip them or  
20 burn them?

21 Q. Correct.

22 A. Yes.

23 Q. They're treated.

24 A. They are treated, yes.

25 Q. So if they're identified and treated, generally speaking,

Hazem Ashhab - Cross (Lewis)

739

1 most of them are done or treated within about a day. That  
2 would be a successful treatment of an AVM or a GI bleed.

3 Is that fair?

4 A. Yes.

5 Q. Okay. So just so I'm clear, if you have a patient, and  
6 they present with a GI bleed that you suspect is an AVM, you  
7 would deem it to be a successful intervention or a successful  
8 treatment if you can repair that complication within about a  
9 day; is that fair?

10 A. Yes.

11 Q. And that is about 90 percent of the folks that you treat,  
12 you do repair or treat successfully within about a day?

13 A. If we are able to identify the source, yes.

14 Q. And that is true for anybody who is on any kind of  
15 anticoagulant medication, right?

16 That would still be a successful treatment if you could  
17 get after that complication and get it repaired within a day;  
18 is that right?

19 A. Yes.

20 Q. Okay. Let's about talk about Mrs. Knight for a couple of  
21 minutes.

22 Now you've had a chance, as part of your work in this  
23 case, to review a lot of medical records related to  
24 Mrs. Knight; is that fair?

25 A. Yes.

Hazem Ashhab - Cross (Lewis)

740

1 Q. And you feel like you've reviewed all of the records that  
2 you need to review to form your opinions?

3 A. I believe so.

4 Q. And you've seen the medical histories dating back in time  
5 maybe six, seven, maybe more years; is that fair?

6 A. Yes.

7 Q. All right. And you've read the home health care records  
8 and the doctors' notes and the reports from office visits,  
9 things like that; is that right?

10 A. Yes.

11 Q. You would agree that Mrs. Knight, at the time that she  
12 first went on an anticoagulant medication, which was warfarin,  
13 she needed it?

14 Fair to say?

15 A. Yes.

16 Q. Okay.

17 MR. LEWIS: And if we could get the opening slide  
18 related to the risk factors.

19 Q. You actually -- as part of your work in this case, you did  
20 look at Mrs. Knight's circumstances -- and I have on the  
21 screen to your left some of the risk factors.

22 But you independently looked to see whether Mrs. Knight  
23 did have a high risk of suffering from stroke based on her  
24 circumstances at the time that she took warfarin; is that  
25 right?

1 A. Yes.

2 Q. Okay. And she did, right?

3 A. Yes.

4 Q. All of these factors -- the age, the fact that she's a  
5 female unfortunately, a prior stroke that she had,  
6 hypertension, vascular disease, diabetes, congestive heart  
7 failure that she was experiencing -- those things increased  
8 Mrs. Knight's risk of a stroke at the time that she began  
9 anticoagulant medication; is that right?

10 A. Yes.

11 Q. And you would agree with me that these risk factors only  
12 got worse with time?

13 A. Yes.

14 There is, however, a discrepancy in the record towards  
15 congestive heart failure because it was not consistent in the  
16 mention. The other factors were all the time consistent. I  
17 just want to point that out.

18 Q. Okay. Periodic congestive heart failure, is that fair to  
19 characterize it that way?

20 A. Maybe.

21 Q. Okay. There were lots of instances in the record where  
22 Mrs. Knight had experienced heart failure symptoms; is that  
23 right?

24 A. That's true.

25 Q. Okay. She had a history of heart attacks?

1 A. Yes.

2 Q. And there's no question in your mind that she was an  
3 appropriate patient for anticoagulant medication.

4 Fair to say?

5 A. Yes.

6 Q. Okay.

7 MR. LEWIS: Finished with that slide. Thank you.

8 Q. Now, you know that in 2005, Mrs. Knight began to take  
9 warfarin or coumadin as a medication, an anticoagulant  
10 medication, right?

11 A. Yes.

12 Q. All right. You reviewed medical records beginning in  
13 2007; is that right?

14 A. Around that time, yes.

15 Q. All right. And there were a handful of physicians that  
16 prescribed warfarin and treated Mrs. Knight between 2005 and  
17 2007; is that right?

18 A. Yes.

19 Q. Those are records that you haven't reviewed, correct?

20 A. I did not review all those, no.

21 Q. So sitting here today, we don't know -- based on the  
22 records, the medical records that were made available to you,  
23 we don't know how she did on warfarin when she first took it  
24 for the first two years; is that right?

25 A. I believe the records I have start around 2008 --

1 Q. Okay.

2 A. -- on through 2013.

3 Q. Okay. So 2005, '06 and '07, those are just records that  
4 you didn't have an opportunity to review?

5 A. That's correct.

6 Q. Did you want to see those, if they were available?

7 A. I'm not sure how relevant they would be.

8 Q. Would you want to have known if Mrs. Knight had  
9 experienced a prior bleed on warfarin in that time frame?

10 A. Yeah. That would be important information.

11 Q. Would you want to have known if Mrs. Knight had  
12 experienced stroke during that time frame?

13 A. They mention in the record that she had a previous history  
14 of stroke, so we knew it happened before 2008.

15 Q. Okay.

16 A. That's in the record.

17 Q. When Mrs. Knight started on warfarin in 2005, she was at  
18 less risk of a stroke than she was later on in her life.

19 Is that fair to say?

20 A. Because she got older.

21 Q. And many of the things that caused her to have high stroke  
22 risk in 2005 continued to get worse over time; is that right?

23 A. Yes, sir.

24 Q. So that risk became increased?

25 A. Yes.

1 Q. Fair to say?

2 Now in 2005, when Mrs. Knight went on warfarin, there was  
3 really one choice for anticoagulant medication, right,  
4 warfarin?

5 A. Yes.

6 Q. All right. Pradaxa wasn't on the market until 2010,  
7 right?

8 A. Yes.

9 Q. And these other medications, such as Xarelto and Eliquis,  
10 weren't available until later either, correct?

11 A. Yes.

12 Q. All right. And warfarin at the time was really the number  
13 one and really the only medication to treat folks who had  
14 AFib, atrial fibrillation -- the jury has heard AFib -- with a  
15 significant stroke risk?

16 A. Yes.

17 Q. The thing about warfarin, though, is it did come with some  
18 risks, right?

19 A. Yes.

20 Q. One of the risks is if you thin the blood, you can  
21 obviously have bleeding events, right?

22 A. Yes.

23 Q. Warfarin has that same risk, and it's a significant risk,  
24 right?

25 A. Yes.

1 Q. Okay. The other thing about warfarin is, is it's kind of  
2 tough to keep it within the therapeutic range.

3 Fair to say?

4 A. Yes.

5 Q. There's a therapeutic range with warfarin, and it's  
6 measured by looking at INR levels. INR, the jury has heard  
7 that.

8 A. Yes.

9 Q. You're familiar with that?

10 A. Yes.

11 Q. And I think that is International Normalized Ratio is what  
12 that stands for, right?

13 A. Correct.

14 Q. All right. And the key is you want to keep that  
15 therapeutic range, you want to keep the INR levels with a  
16 patient generally between 2 and 3; is that right?

17 A. Yes.

18 Q. And if you go below 2, you're going to increase the risk  
19 of stroke; is that right?

20 A. Yes.

21 Q. And if you go above 3, then you're going to increase the  
22 risk of a bleeding event to occur; is that right?

23 A. Yes.

24 Q. So it's really, really important to keep those INR levels  
25 between 2 and 3; is that right?

1 A. Yes.

2 Q. And that can be a problem for folks as they get older to  
3 keep the range between 2 and 3; is that right?

4 A. Yes.

5 Q. Gotta be very careful with your diet, correct?

6 A. Yes.

7 Q. Gotta be very careful with what other medications you're  
8 taking, correct?

9 A. Yes.

10 Q. You gotta be careful with what you eat, right?

11 A. Yes.

12 Q. And you gotta make sure that you go to the doctor on a  
13 regular basis and that you get to the physician's office to  
14 have those blood levels monitored, correct?

15 A. Correct.

16 Q. And all of those things need to happen in order to  
17 maintain that therapeutic range with warfarin, right?

18 A. Yes.

19 But doctors have also designed and came up with a warfarin  
20 clinic. So some of these challenges are really managed  
21 through a designed clinic that provides information about diet  
22 and look at medication interaction and make sure the patients  
23 get their blood tested on time or send a nurse or a home  
24 health care to do their blood. So it's not always the patient  
25 has to actually come to the doctor to have it done. There are

1 other ways to make life easier to monitor their INR.

2 Q. But, Doctor --

3 A. But it has to be monitored, you're right.

4 Q. Okay. Thank you.

5 If you could answer my question, I promise I'll get you  
6 out of here today. If you don't, I can't promise you  
7 anything. Okay?

8 All right. Fair enough, though.

9 A. It's not a threat. It's a promise, not a threat.

10 Q. That's right, only promises.

11 A. All right.

12 Q. All right. But let's be fair, there are some physicians  
13 who have made it a little bit easier to get blood tested when  
14 they have a patient on warfarin than others.

15 Fair to say?

16 A. Yes.

17 Q. They've sort of designed their office around helping  
18 patients make it a little easier because it's really, really  
19 important to keep the blood within that therapeutic range,  
20 right?

21 A. Yes.

22 Q. That's why doctors have set up these special circumstances  
23 and situations to make it easier for patients, right?

24 A. I meant to say there is a warfarin clinic that doesn't  
25 belong to any certain doctor.

1 Q. Sure.

2 A. We can refer them to the warfarin clinic to help them.

3 Q. Right.

4 A. That's what I meant.

5 Q. Right.

6 There are clinics that have been set up to make it easier  
7 for patients, right?

8 A. Yes.

9 Q. Because it's so important to keep those levels between 2  
10 and 3, right?

11 A. Yes.

12 Q. Because the last thing we want are patients who are  
13 outside of that 2 and 3 because then the risks increase,  
14 correct?

15 A. Yes.

16 Q. All right. Fair enough.

17 Now, have you reviewed the label for warfarin? I assume  
18 you have --

19 A. Yes.

20 Q. -- when you treat patients.

21 A. Yes.

22 MR. LEWIS: It's Exhibit 5861, the very first one in  
23 your binder.

24 At this time, Your Honor, I'll move for the admission  
25 of 5861, Defendant's 5861 into evidence.

Hazem Ashhab - Cross (Lewis)

749

1 THE COURT: Any objection?

2 MR. CHILDERS: No, Your Honor.

3 THE COURT: It's admitted. It may be published.

4 (DEFENDANT'S EXHIBIT 5861 ADMITTED INTO EVIDENCE.)

5 MR. LEWIS: Let's take a look at the first page,  
6 Doctor.

7 Q. These labels for medicines look similar, they're designed  
8 similarly.

9 Is that fair to say?

10 A. Yes.

11 Q. One of the things that you see is up in the upper  
12 left-hand corner, there is a lot of important information  
13 usually in that spot, right?

14 A. Yes.

15 Q. In the warfarin label from 2011, we see that down in the  
16 bottom right-hand corner. No question about it, coumadin or  
17 warfarin -- that's the same, it's the same medicine, right?

18 A. Yes.

19 Q. Can cause major or fatal bleeding, correct?

20 A. Yes.

21 Q. Perform regular monitoring, that's what we talked about,  
22 correct?

23 A. Yes.

24 Q. Drugs and dietary changes can affect INR levels. That's  
25 important, we talked about that, right?

1 A. Yes.

2 Q. And then obviously instruct patients to minimize the risk  
3 of bleeding and to report signs. That's in a box in the upper  
4 left-hand corner. That means it's really, really important  
5 information; is that right?

6 A. Correct.

7 Q. All right. And if we look at the right-hand side, Adverse  
8 Reactions, most common adverse reactions to coumadin are fatal  
9 and non-fatal hemorrhage from any tissue or organ.

10 That's a bleed, right?

11 A. Yes.

12 Q. Then you can have with warfarin life-threatening bleeds  
13 just like you described, correct, where there is several pints  
14 of blood that have to be transfused, right?

15 A. Yes.

16 Q. That can happen on warfarin, right?

17 A. Usually not in the therapeutic range. When somebody is  
18 over-anticoagulated, it may happen.

19 Q. Somebody who is outside of the range --

20 A. Yes.

21 Q. -- is more likely to get a very, very serious  
22 life-threatening bleed.

23 Fair to say?

24 A. That's correct.

25 Q. Probably in the range of about 3, not below. But you're

Hazem Ashhab - Cross (Lewis)

751

1 probably more likely to get a life-threatening bleed if you're  
2 outside and higher than that INR level of 3; is that right?

3 A. Usually more than 5 or even 10.

4 Q. Okay. And you agree with me that the most serious risk  
5 for patients who are on warfarin is a bleed risk when their  
6 INR levels are outside of the range, right?

7 A. Yes.

8 Q. Okay. Now, there's also a section called  
9 Contraindications, and that is going to be on page -- it's  
10 going to start on page 5861-009. There are numbers at the  
11 bottom of the page.

12 A. Okay.

13 Q. And if we go to the next page, 010, these are  
14 contraindications, and the fifth bullet point down:  
15 Unsupervised patients with conditions associated with  
16 potential high level of noncompliance.

17 You know what that means, don't you, Doctor?

18 A. Where was that again?

19 Q. Sure. That is --

20 A. Page 10?

21 Q. -- on page 5861-010, fifth bullet point down, right after  
22 the --

23 A. Yes. Unsupervised with conditions associated with  
24 potential high level of noncompliance. Yes, I found it.

25 Q. Right.

1 And noncompliance is patients who don't take their  
2 medication on a regular basis or perhaps forget it, right?  
3 That could be noncompliance, correct?

4 A. Yes.

5 Q. Or patients who aren't able to or won't go to the doctor  
6 and have -- or a clinic and have their blood tested on a  
7 regular basis, correct?

8 A. Correct.

9 Q. Because patients who make it difficult to monitor the INR  
10 levels are patients who are at a higher risk of bleed or  
11 stroke, right?

12 A. Yes.

13 Q. And in fact, these patients are contraindicated by the  
14 label. Is that fair to say?

15 A. Yes.

16 Q. Okay. And that would include patients who may be  
17 suffering from dementia and are having trouble remembering  
18 whether they took their medication as well, correct?

19 A. Yeah. If they have no care provider to give it to them,  
20 yes.

21 Q. And we know also later in the label, pages 14 and 15,  
22 discuss the various interactions.

23 You're aware, Doctor, that there are many, many drug  
24 interactions that affect warfarin in a patient, right?

25 A. Yes.

1 Q. And if we look at the CYP450 interactions -- do you know  
2 what that means?

3 A. Yes. That is a measure, cytochrome p450 in the liver.  
4 That is responsible for a whole type of metabolism of  
5 medications. I cannot name how many there are. Almost  
6 everybody goes through cytochrome p450. So --

7 Q. All right. Most medications are metabolized through the  
8 liver, or many of them, right?

9 A. Yes.

10 Q. And warfarin is one of those medications?

11 A. Yes.

12 Q. And if you have another medication that is metabolized  
13 through the liver that you're taking, it can really affect  
14 your warfarin absorption, correct?

15 A. Yeah, if they are inducers or inhibitors. So some  
16 potentiate the effect, and some inhibit the effect.

17 Depends on the action of --

18 Q. It depends. One could do one thing, and one could do  
19 another, right?

20 A. That's true.

21 Q. And if you look at the next page, we have examples of  
22 these inhibitors, right, that --

23 A. Yes.

24 Q. -- you have to watch?

25 And there's a whole laundry list of those potential

1 medications that can affect warfarin levels, right?

2 A. That's true.

3 Q. So if you have a patient that is on a lot of other  
4 medications, that can be a real problem to manage that  
5 patient's warfarin, correct?

6 A. Yes.

7 Q. All right. And I think we already discussed the fact that  
8 foods can affect it, too. A lot of leafy greens and foods  
9 with vitamin K can affect the warfarin interaction; is that  
10 right?

11 A. Yes.

12 Q. If we look at the page -- and I'll just go to page  
13 5861-31, you see that warfarin also comes with a Medication  
14 Guide just like Pradaxa. Just like all anticoagulant  
15 medications, there's a Medication Guide, and so I want to ask  
16 you a couple of questions about that.

17 First of all, you agree with me that a Medication Guide  
18 shouldn't have all of the technical information that a  
19 physician label has, correct?

20 A. Yeah.

21 Q. These are made for patients, right? And it needs to be  
22 more simpler language so the common person can understand it,  
23 right?

24 A. Yes.

25 Q. All right. And you see here, what is the most important

Hazem Ashhab - Cross (Lewis)

755

1 information I should know about coumadin, can cause bleeding  
2 which can be serious and sometimes lead to death.

3 MR. CHILDERS: Judge, could we have a side bar?

4 THE COURT: Yes.

5 (Bench conference, reported.)

6 MR. CHILDERS: Your Honor, I didn't ask any questions  
7 about the Medication Guide. I --

8 THE COURT: With respect to coumadin?

9 MR. CHILDERS: With respect to either. I only asked  
10 about the physician label, not the Medication Guide. So  
11 Mr. Lewis is outside the scope.

12 MS. JONES: I mean, the theory in the case is that  
13 your Medication Guide was deficient. I don't know how you can  
14 separate one from the other. I mean, they are basically  
15 saying we didn't warn patients about the risks associated with  
16 this particular drug. I mean, that's the heart of the case.

17 THE COURT: But this is not the expert who is  
18 supplying that. Certainly not with respect to the Medication  
19 Guide that refers to Pradaxa, but nothing like this was in his  
20 examination of the doctor pertaining to warfarin or coumadin.

21 MR. LEWIS: Well, the testimony was that if she were  
22 on warfarin, she would have been okay. And because she  
23 wasn't, she wasn't okay. She was on Pradaxa.

24 So I'm showing two things with the Medication Guide.  
25 Number one is that the information we supplied to

Hazem Ashhab - Cross (Lewis)

756

1 physicians -- and by the way, the Medication Guide is provided  
2 to physicians, the Medication Guide is also provided to  
3 physicians, so this is within the realm of something that a  
4 physician would review. So that's number one.

5 Number two is it also goes to causation, that warfarin  
6 has the same risks associated with it as Pradaxa does.

7 MR. CHILDERS: I didn't object to that from the label  
8 because I asked him about the physicians label. Dr. Plunkett  
9 talked about the Medication Guide. That would have been the  
10 witness to ask these questions to. He's not testified at all  
11 about the Medication Guide. All he has talked about is the  
12 physician label.

13 THE COURT: But he's also testified doctors receive  
14 the Medication Guides and consult them as well, so I'm going  
15 to allow it.

16 MR. CHILDERS: I didn't ask him that.

17 THE COURT: That's what I'm saying.

18 Your witness has testified --

19 MR. CHILDERS: I understand. Okay.

20 Thank you, Your Honor.

21 (Bench conference, concluded.)

22 MR. LEWIS: Just to pick up where I left off, the  
23 Medication Guide for warfarin or coumadin says: Coumadin can  
24 cause bleeding which can be serious and sometimes lead to  
25 death.

Hazem Ashhab - Cross (Lewis)

757

1 Q. And that's right there for patients to see, right, Doctor?

2 A. Yes.

3 Q. All right. And if we scroll a little bit further down, we  
4 see you may have a higher risk of bleeding if you take  
5 coumadin and -- and there is a whole laundry list of other  
6 things. Just like Pradaxa has some things that increase the  
7 risk of bleeding, coumadin has the same thing, correct?

8 A. Yes.

9 THE COURT: Pull that microphone down just a little  
10 bit.

11 THE WITNESS: Yes. But be careful with this data  
12 because it plays against some of the stuff you started with.

13 So, for example, No. 4 says history of stroke. But  
14 you, just in your introduction, told me we give the blood  
15 thinner to prevent stroke. So if this wording was correct,  
16 then she wouldn't get coumadin or any blood thinner, but  
17 that's not the truth.

18 See, there's a difference in practice when you have a  
19 patient to treat between what is in the paper and what is in  
20 the trials and what are the risks for that particular patient.

21 MR. LEWIS: Wholly agree with you, Doctor. I want to  
22 ask you about that.

23 Q. So you would agree with me that sometimes a doctor has got  
24 to put this label aside and treat a patient, that particular  
25 patient in front of him or her.

1 Fair to say?

2 A. I wouldn't say put it aside. I would say take it into  
3 consideration. But then, on top of that, add special  
4 circumstances for that particular patient that make them maybe  
5 not a candidate for that medication, only actual testing for  
6 that medication.

7 Q. But each one of those inquiries is specific to a  
8 particular patient that is sitting in front of that doctor,  
9 right?

10 A. Exactly.

11 Q. Right.

12 And as a physician, the Medication Guide and the physician  
13 label is informative, correct?

14 A. Yes.

15 Q. But you also use your experience, correct?

16 A. Yes.

17 Q. And you also use your assessment of that patient, correct?

18 A. Yes.

19 Q. And you have to make a risk-benefit decision for that  
20 patient on what the best medication is, right?

21 A. Correct.

22 Q. And you know that in your practice -- in your practice,  
23 you don't actually make those risk-benefit decisions when it  
24 comes to anticoagulant medication, correct?

25 A. Usually the patient comes to me with a problem that

1 happened, and they have already been on the medication.

2 However, I do recommend based on my findings, with the  
3 measurement of the bleeding, recommendations towards whether  
4 the patient should discontinue this medicine or the other, and  
5 discuss it with the prescribing doctor.

6 Q. Fair enough.

7 Just to close out this Medication Guide, the one thing I  
8 wanted to cover was that last bullet point that says: You may  
9 have a higher risk of bleeding if you take coumadin or  
10 warfarin -- sodium, that's the active ingredient, right,  
11 Doctor?

12 A. Yes.

13 Q. If you take it for a long time, right?

14 A. Yes.

15 Q. The longer you're on warfarin, the higher the risk you  
16 have of a bleed, right? That's what it is saying right there.

17 A. Yes.

18 Q. And that is true, right?

19 A. Yes.

20 Q. You know that?

21 A. Yes.

22 Q. Okay.

23 MR. LEWIS: I am finished with that. Thank you.

24 Now, you talked a little bit about Mrs. Knight's  
25 experience on warfarin. And as I recall you testifying, you

Hazem Ashhab - Cross (Lewis)

760

1 indicated that she probably would not have had a bleed if she  
2 were on warfarin in 2013 instead of Pradaxa.

3 Q. Did I get that right?

4 A. Close, but not quite.

5 Q. Okay.

6 A. I said wouldn't have had a life-threatening bleed --

7 Q. Okay.

8 A. -- compared with Pradaxa.

9 Q. Okay. So your testimony is that she may have -- she was  
10 probably just as likely to have had a bleed with warfarin as  
11 she was -- as she did with Pradaxa, the risk was the same?

12 A. No, not as likely. It is more likely to bleed on Pradaxa  
13 as compared with coumadin from the gastrointestinal tract.

14 Q. So what I wanted to ask you about is, you also said she  
15 had -- she was well managed on warfarin? Is that what you had  
16 indicated?

17 A. I don't think that came up in the discussion. I said she  
18 was managed on coumadin with monitoring INR.

19 Q. Understood.

20 So do you believe, is it your opinion that she was managed  
21 successfully while she was on warfarin or coumadin?

22 A. To the best of my recollection of the record, that she had  
23 sometimes INRs that were above the desired range. But I do  
24 not recall that she ever had a gastrointestinal bleed on  
25 coumadin. For sure, she did not have any life-threatening

1     bleeding on coumadin for that time that I viewed.

2     Q.   But you agree that when the INR levels are out of the  
3     therapeutic ranges, there is a significant risk of bleed if  
4     they are significantly above 3?

5     A.   I said significant bleed usually we see above 5 and 10,  
6     not just above 3.  Because there are some people whose  
7     therapeutic range is really up to 3 and a half, for example,  
8     and that is their desired range.  So I usually, in my over 20  
9     years of experience, do not see GI bleeds with an INR of 2 and  
10    a half, 3, 3 and a half or even close to 4.  Very, very  
11    rarely.  The ones I see are usually INR way high above 5 and  
12    above 10.

13           MR. LEWIS:  All right.  Well, let's go to an opening  
14    slide on the INR levels.  This was shown in opening by  
15    Ms. Jones.

16    Q.   And you looked at all of the medical records associated  
17    with the INR readings for Mrs. Knight, right?

18    A.   The ones that were provided to me --

19    Q.   Right.

20    A.   -- I did.

21    Q.   And there were a lot of INR readings, correct?

22    A.   Several ones, yes.

23           MR. LEWIS:  Your Honor, we've prepared a summary of  
24    the INR levels that has been marked as Defendant's Exhibit  
25    9009S.  It's a Rule 1006 summary.  I would move for the

1 admission of that summary at this time.

2 THE COURT: Any objection?

3 MR. CHILDERS: I'm going to object to the admission as  
4 an exhibit. If it's a demonstrative, that's fine, but I don't  
5 believe this has been authenticated, a foundation hasn't been  
6 laid for it. So --

7 THE COURT: So is it a demonstrative exhibit?

8 MR. LEWIS: This is a demonstrative. I have a summary  
9 that is not a demonstrative that is being moved into evidence  
10 that I've provided to Mr. Childers.

11 THE COURT: And this chart purports to represent the  
12 document you just referred to that is the summary of all of  
13 her INR reports?

14 MR. LEWIS: Correct. And we've made the documents  
15 available to Mr. Childers. In fact, I provided those to  
16 opposing counsel this morning as back-up, but they were  
17 medical records that were already exchanged.

18 THE COURT: All right. On that representation, I'll  
19 allow you to use them.

20 MR. LEWIS: So could we pull up 9009S.

21 All right. So this is a very generic chart that is in  
22 front of you. And this is just charts in the medical records  
23 as 9009S, charts in the medical records, the INR readings from  
24 the various medical records over time.

25 And if we just scroll down, you can see that there

Hazem Ashhab - Cross (Lewis)

763

1 is -- the numbers change over time. There's a date, the  
2 numbers are in the middle. You can see that.

3 And you can see that there is --

4 THE WITNESS: Do I have that in here? Do I have this  
5 here?

6 MR. LEWIS: You have it in front of you. It is  
7 towards the back of your binder, and it would be 9009S.

8 THE WITNESS: Okay.

9 BY MR. LEWIS:

10 Q. You reviewed the INR levels for Mrs. Knight, though, as  
11 part of your work in this case, right?

12 A. Yes.

13 Q. And so you know that she spent more time out of  
14 therapeutic range than in therapeutic -- in therapeutic range,  
15 right?

16 Did you ever count them up?

17 A. I didn't really count them up. I looked at them, but I  
18 didn't count them one by one.

19 MR. LEWIS: Well, the demonstrative plots these  
20 numbers, so let's go to that.

21 Q. And you can see here that the therapeutic range in the  
22 demonstrative that is in front of us shows the range 2 to 3,  
23 and the yellow is the therapeutic range. And anytime there's  
24 a white dot, that is outside the therapeutic range, right?

25 A. Yes.

1 Q. And you see that at least on a couple of occasions she had  
2 INR levels as high as 8.

3 That's a serious risk of bleed right there, right?

4 A. Yes.

5 Q. And other levels that approach 6 and were above 6 in other  
6 instances, right?

7 A. Yes.

8 Q. And then several levels below 2. That means that she is  
9 at a higher risk of stroke because she's not within the right  
10 level; is that correct?

11 A. Yes.

12 Q. All right. And you see that over time there was  
13 consistent out-of-range readings on the INR levels. If you  
14 just look at the time frame, it's consistent, right, just like  
15 Dr. MacFarland said?

16 A. Yes.

17 MR. LEWIS: And let's take a look at Mrs. Knight's  
18 circumstances on warfarin in 2008. And if we could -- I am  
19 finished with that exhibit.

20 I'm going to move for the admission of Exhibit 9003A,  
21 which is a sub-exhibit of the medical records similar to what  
22 the plaintiffs have done here.

23 MR. CHILDERS: No objection, Your Honor.

24 THE COURT: It's admitted.

25 (DEFENDANT'S EXHIBIT 9003A ADMITTED INTO EVIDENCE.)

Hazem Ashhab - Cross (Lewis)

765

1 MR. LEWIS: If we look at 9003A. Sorry. Exhibit  
2 9003A.

3 THE WITNESS: 9003, you said?

4 MR. LEWIS: Yes.

5 THE COURT: 3A.

6 THE WITNESS: Thank you, Your Honor.

7 Yes, sir.

8 MR. LEWIS: Are you able to -- do you have that?

9 THE WITNESS: I have, yeah, 9003A.

10 MR. LEWIS: All right. Just to orient ourselves, so  
11 Mrs. Knight -- this is a record from the 2008 time frame  
12 that's in front of you. And --

13 THE COURT: The first page of it is the certification.

14 MR. LEWIS: Sorry. The second page of 9003A. You  
15 have a certification that shows it was --

16 THE WITNESS: Yes.

17 MR. LEWIS: -- authenticated, and now we have the  
18 record itself.

19 THE COURT: It's page 10 in this sequence at the  
20 bottom?

21 MR. LEWIS: Correct.

22 THE WITNESS: This chart summary?

23 MR. LEWIS: Ten at the bottom, 9003-10.

24 THE WITNESS: Yes.

25 MR. LEWIS: Okay. Go to the second page.

1 And we see up in the top, this is -- date admitted was  
2 August 7th of 2008.

3 Q. This is a Dr. MacFarland record; is that right?

4 A. Yes.

5 Q. And we have here Mrs. Knight coming to see Dr. MacFarland  
6 for a number of things, but really acute respiratory failure.

7 If you look at the brief history and hospital course  
8 shortly down, you see that she's had a number of issues. But  
9 she's coming to see Dr. MacFarland because, in the fourth line  
10 down, she called and went to the emergency room with acute  
11 respiratory failure and then eventually wanted to come to see  
12 Dr. MacFarland, right?

13 A. Yes.

14 Q. And if we fast-forward to two thousand -- excuse me --  
15 9003-12, you see under diet, as tolerated?

16 A. Yes.

17 MR. LEWIS: Are you able to scroll through the next --  
18 the same day, it's just two pages -- there you go, she is  
19 currently off.

20 Q. You see Dr. MacFarland is noting that Mrs. Knight is off  
21 coumadin, off warfarin at this time in 2008?

22 A. Yes.

23 Q. She's going to try something else. And Dr. MacFarland is  
24 explaining to her that coumadin is the gold standard, but at  
25 this time Mrs. Knight doesn't want to come to the office to

Hazem Ashhab - Cross (Lewis)

767

1 get the blood work checked as frequently, right?

2 A. Yes.

3 Q. She's declining it at that point in time.

4 Is that fair to say?

5 A. That's what she said, yes.

6 Q. Okay. But if we fast-forward one month --

7 MR. LEWIS: And this is going to be Exhibit 9007, and  
8 I move for the admission of 9007A. Those are medical records.

9 MR. CHILDERS: No objection, Your Honor.

10 THE COURT: They're admitted.

11 (DEFENDANT'S EXHIBIT 9007A ADMITTED INTO EVIDENCE.)

12 MR. LEWIS: 9007A, pages 8 and 9.

13 THE WITNESS: Yes.

14 MR. LEWIS: So we see this is a visit with Dr.  
15 Haberman from a month later, September 18th, 2008.

16 And if you look at the bottom impression, she has a  
17 history of stroke. And Dr. Haberman is saying Mrs. Knight  
18 absolutely needs to get back on her coumadin because her risk  
19 having another stroke, another stroke, is high.

20 Now, if we look at the next page on -- look at No. 3.  
21 This is what Dr. Haberman did. She was on Plavix. Took her  
22 off Plavix and said discontinue Plavix to prevent bleeding  
23 from the concomitant --

24 Q. That means at the same time, right, Doctor?

25 A. Yes.

1 Q. -- aspirin and coumadin therapy.

2 Dr. Haberman, right, Doctor, is expressing a concern about  
3 putting this particular patient on Plavix and warfarin at the  
4 same time.

5 Is that fair to say?

6 A. Yeah. The more blood thinners you have, the higher the  
7 risk of bleed.

8 Q. Right.

9 And that is something that Dr. Haberman is concerned about  
10 as early as 2008, right?

11 A. Yes.

12 Q. So that --

13 A. But also I'm not sure what is the indication here for  
14 Plavix. It was given because she did not want to take the  
15 coumadin. But now that she agrees to the coumadin, she  
16 doesn't need the Plavix. I'm not sure that he needs to stop  
17 it. She doesn't need it.

18 Q. If you read No. 3, it says: Discontinue Plavix to prevent  
19 bleeding from concomitant aspirin and coumadin therapy, right?

20 A. Yeah, I see what you're saying.

21 Q. Right.

22 He considered triple therapy and said no, right?

23 A. Yes.

24 Q. Okay. If we go later into 2008, we talked a little bit  
25 about whether or not she had a bleed. And it's your opinion

1 that she didn't experience a bleed after she went back onto  
2 coumadin at this time; is that right?

3 A. I saw no evidence of that in the chart.

4 Q. Okay. Well, if we go to 9007-19 --

5 A. Dash 19.

6 Q. -- we just see here that this is Mrs. Knight coming in to  
7 see Dr. MacFarland and to discuss some mental status changes.

8 She's experiencing some weakness, right?

9 A. Yes. Yes.

10 Q. Okay. And at this point in time, she's also -- her family  
11 is concerned about -- if you see in the history of present  
12 illness, is concerned about a little bit of her potentially  
13 progressing dementia at the time; is that right?

14 A. Yes.

15 Q. Okay. And there was some concern about that.

16 If we go to 9007-36 and -37 during the same time frame --  
17 if we go to 9007-36, we see that eventually Mrs. Knight works  
18 her way to Dr. Haberman again.

19 A. Yes.

20 Q. And he notes here on the front page -- and this is right  
21 around the same time frame, mid November 2008. She's on  
22 coumadin.

23 And if we go to page 37, the very next page, Dr. Haberman  
24 down in impression, in recommendations says: She is  
25 experiencing anemia, which might be secondary to the recent

1 initiation of coumadin, right?

2 A. That's what it says.

3 Q. He's saying that she might be experiencing a bleed because  
4 of the recent initiation of coumadin, correct?

5 A. That's what it says, yes.

6 Q. That's what he is suspecting here in November of 2008,  
7 right?

8 A. Yes. He's suspected that, yes.

9 Q. Right. Sure.

10 And the very first thing he says in his recommendations is  
11 stop coumadin, right?

12 A. That's what it says, yes.

13 Q. Okay. And if we flip back into 9007-25, we see this is a  
14 consult right around the same time frame, in mid November,  
15 with Dr. Rohrbach.

16 Do you see that on the right-hand side?

17 A. Yes.

18 Q. Now you know Dr. Rohrbach is a GI specialist here in  
19 Huntington, right?

20 A. Yes.

21 Q. Okay. And Dr. Rohrbach says in the history: She has been  
22 seen by Dr. Haberman, and she was found to be anemic.

23 Do you see where it says that in the middle of history?

24 A. Yes.

25 Q. In the emergency room, her hemoglobin was 10. By

1 yesterday it was down to 9.

2 It's dropping, correct, Doctor?

3 A. Yes.

4 Q. Okay. She's been transfused two units.

5 Do you see where it says that?

6 A. Yes.

7 Q. That suggests a blood loss, right, Doctor?

8 A. Well, she has more than one reason to be anemic, but it  
9 did drop from 10 to 9.

10 Q. And she is transfused with two units of blood, right?

11 A. Yes. Yes.

12 Q. That suggests she's losing blood, correct?

13 A. Not always. I hate to get into this, but people can have  
14 hemolysis or can have lack of production or can have bleeding.  
15 But the problem here is nobody documents that they have seen  
16 any blood or tested for any blood.

17 Q. Understood.

18 A. So I don't see a GI bleed here. He's implicating or he's  
19 guessing, but there really -- there is no documentation that  
20 she has GI bleeding --

21 Q. Understood.

22 A. -- and that's the problem.

23 Q. Understood.

24 But the GI specialist is being consulted here, correct?

25 A. Correct.

Hazem Ashhab - Cross (Lewis)

772

1 Q. And he's noting that she is -- her hemoglobin is dropping,  
2 and she's been transfused two units, correct?

3 A. Correct.

4 Q. And then he goes on to say she's had some darker stool,  
5 which is indicative of a potential GI bleed, correct, Doctor?

6 A. Correct.

7 Q. Okay. This GI specialist is suspicious of a GI bleed,  
8 correct?

9 Now you know from the records that eventually a  
10 colonoscopy wasn't done because they felt Mrs. Knight was too  
11 ill. You know that, right?

12 A. That's what it says in the records.

13 Q. Right. Okay.

14 But when we look at what the doctor said later in the  
15 documents that weren't shown to you on direct examination, we  
16 see that they do refer to a GI bleed, right? You know that,  
17 right?

18 A. They mention it in the notes.

19 Q. Right. So --

20 A. But there's no documentation of it.

21 Q. Okay.

22 MR. LEWIS: Let's take a look at the documentation in  
23 Exhibit 9009, which I'll move for admission of at this time.

24 THE COURT: Any objection?

25 MR. CHILDERS: No, Your Honor.

1 THE COURT: It's admitted.

2 (DEFENDANT'S EXHIBIT 9009 ADMITTED INTO EVIDENCE.)

3 MR. LEWIS: If we go on to 9009A, and we go to page  
4 273 and 275 -- we'll just go to 273.

5 Q. We see this is Dr. Gunnalaugsson from December of 2008,  
6 and you see that in the history of present illness, Dr.  
7 Gunnalaugsson is talking about doing a stent procedure,  
8 correct?

9 A. Yes.

10 Q. And he's choosing a bare metal stent, correct?

11 A. Yes.

12 Q. And a bare metal stent is chosen if a doctor is worried  
13 about extensive bleeding because you have to go on less  
14 anticoagulant medication with a bare metal stent.

15 Fair to say?

16 A. Less blood thinners, yes.

17 Q. Yes.

18 And if we go to what Dr. Gunnalaugsson says on page 275  
19 under Assessment and Plan, you see right in the middle: She  
20 has been on coumadin for atrial fibrillation, but this was  
21 stopped because of her chronic bleed.

22 You see where it says that?

23 A. Yes.

24 Q. And then instead, she's on aspirin and Plavix, and they  
25 took her off coumadin, right?

1 A. I see that, yes.

2 Q. Okay. And this is right in the records. This is in  
3 writing, right?

4 A. Yes, I see it.

5 Q. Okay. If we look back at 9007, we see what happens  
6 because she wasn't on coumadin.

7 On 9007-55, we see this is Dr. Linsenmeyer for Mrs. Knight  
8 in February of 2009. Again, Dr. Linsenmeyer is consulting  
9 with Dr. Gunnalaugsson. Mrs. Knight is not on coumadin at  
10 this point. Dr. Gunnalaugsson thinks it's because of prior  
11 bleed.

12 And we say: For the last five days prior to presentation,  
13 the patient noticed that her fingerprints were turning  
14 discolored. She began to experience severe right brachial arm  
15 pain.

16 She has a blood clot here, right, Doctor?

17 A. Yes.

18 Q. She suffers from a blood clot in February of 2009, right?

19 A. Yes.

20 Q. Okay. And this is the constant problem that the  
21 physicians were facing with Mrs. Knight during the entire  
22 course on warfarin, right? This was a problem for them,  
23 wasn't it?

24 A. After they stop it, they got a clot. If they don't stop  
25 it, they have a hard time monitoring it.

1 Q. Right.

2 A. Yeah, it was a challenge. It was a big challenge, yeah.

3 Q. They were having trouble keeping Mrs. Knight on warfarin  
4 within the therapeutic range.

5 Fair to say?

6 A. Fair to say.

7 Q. And we just saw an example where, because her INR levels  
8 were too high, she suffered from a suspected bleed, correct?

9 A. Correct.

10 Q. And when they try to take her off the warfarin to try to  
11 bring the INR levels down, she suffers a clot, right?

12 A. Correct.

13 Q. That's not a well managed warfarin patient, is it, Doctor?

14 A. She seems to have problems either way.

15 Q. Yeah.

16 Difficult, right?

17 A. Difficult, yes.

18 Q. Very difficult.

19 A. A challenging patient.

20 Q. And some patients are like that, correct?

21 A. Correct.

22 Q. Some patients like Mrs. Knight are very, very difficult to  
23 manage on any medication, including warfarin, right?

24 A. Correct.

25 Q. On the one hand, you are darned if you do, and you are

Hazem Ashhab - Cross (Lewis)

776

1       darned if you don't, right?

2       A.   Yes.

3       Q.   And that's what is going on here in 2009 with Mrs. Knight,  
4       right?

5       A.   Correct.

6       Q.   It gets worse by 2011, doesn't it, Doctor?

7       A.   Yes.

8               MR. LEWIS:   In fact, let's go to Exhibit 9009-389.

9               THE COURT:   9009A?

10              MR. LEWIS:   Sorry.   9009A-389.   Sorry, Your Honor.

11              Let's look at the last seven days Mrs. Knight was on  
12       warfarin.   Day one, October 10, 2011, Dr. MacFarland gets a  
13       call.   Mrs. Knight's INR levels are at 8 again.

14       Q.   You see that on the message, 9009-389?

15       A.   Oh, 389.

16       Q.   Sorry.

17       A.   Yes.

18       Q.   INR of 8; you see that?

19       A.   Yes.   Yes.

20       Q.   That is serious, right?

21       A.   Yes.

22       Q.   Here she is at a bleed risk again, correct?

23       A.   Yes.

24       Q.   Dr. MacFarland says go to the ER, right?

25       A.   Yes.

Hazem Ashhab - Cross (Lewis)

777

1 Q. And you see a note here that the wait maybe at the ER was  
2 too long or was called in, and she couldn't get her in. So  
3 call in vitamin K.

4 That's the antidote, right?

5 A. Yes.

6 Q. All right. And then if we go to 9009-385, two days later,  
7 her INR is 5.

8 That is still high, right, Doctor?

9 A. Yes.

10 Q. Dr. MacFarland is saying hold the coumadin tonight, don't  
11 take it, recheck the INR tomorrow, correct?

12 A. Yes.

13 Q. If we go to 9009-383, a day later, her INR is back up to  
14 6.3.

15 That's a high risk of bleed still, right?

16 A. Yes.

17 Q. So now we're on day three of high risk of bleeding for  
18 Mrs. Knight in October of 2011, correct?

19 A. Yes.

20 Q. All right. If we go to 9009-448, we see in the middle the  
21 INR reading is now down to 4.6.

22 Do you see that?

23 A. Yes.

24 Q. It's getting better, it's improving, correct?

25 A. Yes.

1 Q. The doctor says take vitamin K, and we're going to recheck  
2 the INR, correct?

3 A. Yes.

4 Q. If we go to 9009-425, it is a handwritten note, kind of  
5 hard to read.

6 A. Oh, yes.

7 Q. But if we look at the data reviewed towards the bottom of  
8 425, we see now that they've overshoot this. Now the INR is at  
9 1.6.

10 A. Yes.

11 Q. Data reviewed, the INR is now at 1.6.

12 Now she's back on the high risk of stroke, right?

13 A. Yes.

14 Q. During this entire time, none of these readings are within  
15 the therapeutic range, correct?

16 A. Yes. That's why you send these people to the warfarin  
17 clinic.

18 Q. The doctors are struggling to keep Mrs. Knight in the  
19 therapeutic range, right, Doctor?

20 A. Yes.

21 Q. And look at what is said in the upper left-hand corner of  
22 this document: Want to replace coumadin. New medication,  
23 Pradaxa.

24 There's nothing about a TV ad in here, is there?

25 A. I don't see it here.

1 Q. What's going on here when the switch is made from coumadin  
2 to Pradaxa is that the doctors were struggling to keep her  
3 safe on warfarin, right?

4 A. That's what this record says.

5 Q. Okay. And let's look at what Dr. MacFarland herself said  
6 on 9009-580.

7 A. Dash five --

8 Q. Dash 580, 9009A-580.

9 A. Got it.

10 Q. You know, sometimes you probably have done this, you had  
11 to fill out forms to justify medications?

12 A. Yes, sir.

13 Q. And when you do that, it's important to tell the truth and  
14 be honest and accurate about that; is that right?

15 A. Yes, sir.

16 Q. Okay. And Dr. MacFarland is filling out this form on  
17 October 18th of 2011, after these seven or eight days of never  
18 having Mrs. Knight within a safe range to use warfarin, right?

19 A. Yes.

20 Q. And the diagnosis is: Sporadic and supratherapeutic on  
21 coumadin. Do you see that?

22 A. Yes.

23 Q. That means they can't keep her within a safe range, right?

24 A. Correct.

25 Q. And if we look at the next page, 9009-581: Patient is

1 sporadic and supratherapeutic on coumadin since 2008 until  
2 present.

3 That's what Dr. MacFarland says in October of 2011, right?

4 A. Yes.

5 Q. That's what she said to justify the switch from warfarin  
6 to Pradaxa in 2011, right?

7 A. Yes.

8 Q. Warfarin wasn't working for her. Warfarin wasn't working  
9 for Mrs. Knight. Do you agree with that?

10 A. That's what the record reflects. It depends on what you  
11 mean by not working. It was given to prevent stroke. I don't  
12 see a record here that she had any stroke during the coumadin  
13 period.

14 Q. You would agree with me that Dr. MacFarland is expressing  
15 an opinion here that she needs to go off warfarin because she  
16 can't control the therapeutic range with Mrs. Knight, correct?

17 A. That's correct. That statement is correct.

18 Q. It doesn't say anything about a TV ad in this document --

19 A. Uh-huh.

20 Q. -- right?

21 A. Correct.

22 MR. LEWIS: All right. Now let's talk about -- you  
23 reviewed the records -- I'm finished with that. Thank you  
24 very much.

25 Q. You reviewed the records for Mrs. Knight's Pradaxa use,

1 correct?

2 A. Yes.

3 Q. And you're familiar with the fact that before this stent  
4 procedure in April of 2013, so between October of 2011 and  
5 April of 2013, Mrs. Knight was on Pradaxa, correct?

6 A. Correct.

7 Q. Okay. And in April of 2013, she had a stent procedure,  
8 correct?

9 A. Correct.

10 Q. We're going to talk about that in a second.

11 But between October of 2011 and April of 2013, while Mrs.  
12 Knight was on Pradaxa, she didn't suffer a stroke, and she  
13 didn't suffer a bleed event, correct?

14 A. Correct.

15 Q. And that's 18 months, correct?

16 A. Correct.

17 Q. And then something happened in April of 2013, correct?

18 A. Correct.

19 Q. She had a stent procedure.

20 And if we go to 9007-94 --

21 A. 9007 --

22 Q. 9007A-94. This is April 22nd, 2013, from Dr. Maru, right?  
23 Referring physician, Dr. Graham.

24 A. Yes.

25 Q. Okay. Now, just to help orient the jury, by this time Dr.

1 MacFarland is no longer treating Mrs. Knight, correct?

2 A. It seems like it.

3 Q. She has switched physicians by this time, correct?

4 A. Okay.

5 Q. And so the decisions on prescribing Pradaxa in 2013 are no  
6 longer being made by Dr. MacFarland, correct?

7 A. Yes.

8 Q. Other physicians are involved in this, correct?

9 A. Yes.

10 Q. All right. And you see here in the procedure, bare metal  
11 stent -- again, that's a stent placed to avoid having to be on  
12 blood thinners too long, correct?

13 A. Yes.

14 Q. Okay. Was placed.

15 And if we go to 9007-0095, we see under Conclusion a  
16 recommendation: Continue aspirin indefinitely and Plavix for  
17 a minimum of four weeks, preferably longer if the patient can  
18 tolerate it. Resume her Pradaxa tonight.

19 Now let's look at what the next line says.

20 By the way, Dr. Maru is a cardiologist. Did you know  
21 that?

22 A. From the record.

23 Q. Okay. Due to triple therapy -- and you know what triple  
24 therapy is, right?

25 A. Yes.

1 Q. That's aspirin, Plavix and Pradaxa. That's called triple  
2 therapy, right?

3 A. Yes. In her case, yes.

4 Q. In her case. It might mean something different in a  
5 different context.

6 A. Yes.

7 Q. Okay. Due to triple therapy, I am not sure the patient  
8 will tolerate long-term Plavix, so minimum would be four  
9 weeks, and that's the main reason bare metal stenting was  
10 chosen during this PCI procedure.

11 Do you see that?

12 A. Yes.

13 Q. Okay. So the doctor here is concerned that it's the  
14 Plavix that Mrs. Knight won't tolerate in this triple therapy,  
15 right?

16 A. That's what he says.

17 Q. And that's the thing that is going to change here in April  
18 of 2013, right?

19 A. That's what he said. He added Plavix, yes.

20 Q. Because during the 18 months that Mrs. Knight was on  
21 Pradaxa before the stent procedure, she was taking Coreg,  
22 right?

23 A. According to the record.

24 Q. She was taking aspirin, right? Omeprazole, a P-gp  
25 inhibitor?

1 A. Yes.

2 Q. Coreg is a P-gp inhibitor?

3 A. Yes.

4 Q. She was taking those medications from October of 2011 to  
5 April of 2013, right?

6 A. That's true.

7 Q. No stroke, no bleeding, correct?

8 A. Yes.

9 Q. The one thing that changed was adding Plavix to the  
10 medication profile in April of 2013, correct?

11 A. Yes.

12 Q. That's what changed.

13 And you would agree with me that Plavix has a risk,  
14 independently of being mixed with Pradaxa or aspirin, of  
15 bleed?

16 A. Yes.

17 Q. Just like other anticoagulant medications, Plavix too has  
18 a risk of bleeding?

19 A. Yes. All of them do.

20 Q. All of them do.

21 And when you mix more than one blood thinner, you increase  
22 the risk of bleed?

23 A. That's true.

24 Q. Okay. And when you increase the risk of bleed with other  
25 risk factors such as age, you're compounding the risk of

1 bleed, correct?

2 A. Correct.

3 Q. But you don't criticize the decision to put Mrs. Knight on  
4 Plavix, Pradaxa and aspirin in April of 2013, do you?

5 A. I'm not in that position to make a decision. The  
6 cardiologist put a stent, and he wanted to protect the stent,  
7 so that's his decision.

8 Q. Right.

9 Because once you put in a stent, you run a higher risk of  
10 stroke, right?

11 A. Not from the stent, no. He put the Plavix to prevent the  
12 stent from clotting.

13 Q. Correct.

14 You have a high --

15 A. But the stent doesn't cause a stroke.

16 Q. You have a higher risk of blood clots, correct?

17 A. In the stent.

18 Q. Correct, with a stent.

19 A. In the stent.

20 Q. Yes, in the stent --

21 A. Yes.

22 Q. -- itself. Okay. Let me get this right. Thank you for  
23 correcting me.

24 When you put in a stent, you run an independent risk of  
25 higher risk of blood clots in the stent, correct?

1 A. Yes.

2 Q. Okay. And to counteract that, physicians will sometimes  
3 prescribe Plavix; is that right?

4 A. Yes.

5 Q. Okay. So at the time that Mrs. Knight is having her stent  
6 procedure in April of 2013, the doctor is concerned about  
7 blood clots because of the stent, right?

8 A. Yes.

9 Q. She still needs an anticoagulant like Pradaxa, right?

10 A. Yes.

11 Q. And they're giving her aspirin as well because they are  
12 concerned about the stroke risk, right?

13 A. Correct.

14 Q. Okay. But, of course, that comes with a higher risk of  
15 bleeding, right?

16 A. Correct.

17 Q. And these doctors are trying to make difficult decisions  
18 with a patient who has lots of risk factors, right?

19 A. Correct.

20 Q. Fair to say?

21 A. Uh-huh. Correct.

22 Q. Okay. And it is another one of those darned if you do,  
23 darned if you don't situations, correct?

24 A. It is difficult.

25 Q. All right. And, of course, you have already covered some

Hazem Ashhab - Cross (Lewis)

787

1 of the documents related to -- and I'm finished with that --  
2 Mrs. Knight's bleed event that took place in May of 2011,  
3 right? You covered that.

4 Okay. You know that she was treated by a GI specialist  
5 called Dr. Huh; is that right?

6 A. Yes.

7 Q. Okay. So let me see if I can get some of these facts out.

8 Mrs. Knight was brought in to see Dr. Abdelgaber after she  
9 had witnessed some bleeding for about six days.

10 Do you recall that?

11 A. Yes. Yes.

12 Q. Okay. So she had been experiencing some bleed symptoms  
13 for about six days, correct?

14 A. I'm not sure if it's six. It says a few days --

15 Q. A few days.

16 A. -- in the record, yes.

17 Q. Okay. So a few days before she sees Dr. Abdelgaber,  
18 correct?

19 A. Yes.

20 Q. And then when she sees Dr. Abdelgaber, he refers Mrs.  
21 Knight to Dr. Huh, correct, the GI specialist?

22 A. Yes.

23 Q. Okay. And Dr. Huh on May 20th of 2013 sees Mrs. Knight,  
24 correct?

25 A. Yes.

1 Q. He assesses her?

2 A. Yes.

3 Q. She was in stable condition, correct?

4 A. I have to look at the record.

5 Q. Go ahead.

6 A. Was that that time she was admitted?

7 Q. Correct.

8 A. Yeah. The gastroenterologist saw her after she received  
9 the blood.

10 Q. Absolutely.

11 A. So she was relatively stabilized.

12 Q. Okay. She was stabilized.

13 And in fact, Dr. Huh did not immediately perform a  
14 procedure on Mrs. Knight --

15 A. That's correct.

16 Q. -- is that correct?

17 He actually let her stay in the hospital overnight,  
18 correct?

19 A. Yes.

20 Q. And said that I'm going to handle this procedure in the  
21 morning, correct?

22 A. Yes.

23 Q. And then the next morning, Dr. Huh came in, and he did a  
24 colonoscopy, correct?

25 A. Yes.

1 Q. And he found when he did the colonoscopy an AVM, correct?

2 A. Yes.

3 Q. And he treated it, correct?

4 A. Yes.

5 Q. He stopped the bleeding?

6 A. Correct.

7 Q. He stabilized her?

8 A. Further, yes.

9 Q. Within 24 hours of presenting to Dr. Huh, Mrs. Knight was  
10 stabilized, and her AVM was treated, correct?

11 A. Correct.

12 Q. And it was treated successfully at that time, correct?

13 A. Correct.

14 Q. The bleeding stopped?

15 A. Correct.

16 Q. Okay. She was allowed to leave the emergency situation of  
17 having an AVM that needs treatment, correct?

18 A. Correct. For the AVM, yes.

19 Q. For the AVM.

20 It was -- it was repaired, right?

21 A. Yes.

22 Q. Okay. That would be a successful repair of an AVM by your  
23 own definition, correct?

24 A. Yes. If you clip it, and the bleeding stops, then the job  
25 is done.

1 Q. Okay. Now later on that year, 2013, there's a question  
2 about whether or not Mrs. Knight should go back on the Plavix,  
3 isn't there?

4 A. Yes.

5 Q. And then if we go to 9007-146, this is from August 23rd of  
6 2013, and we see this is one of the doctors -- referring is  
7 Dr. Abdelgaber, and one of the consultants is Dr. Snavelly.  
8 You see the reason for consultation is elevated troponin.

9 That is suggestive of a possible heart attack, isn't it,  
10 Doctor?

11 A. Yes.

12 Q. When there is elevated troponin, it's a big red flag for  
13 physicians that a patient may be experiencing a serious heart  
14 condition, correct?

15 A. Yeah. Depending on the clinical scenario, but yes.

16 Q. Okay. And we see that in the third paragraph, it says:  
17 The patient states that she's been doing fairly well in her  
18 typical state of health, but she did begin to have some  
19 heart -- some chest pains essentially, correct?

20 A. Yes.

21 Q. Okay. And when we go to 9007-148, 9007A-148, we see  
22 there's a plan.

23 A. Yes.

24 Q. And you see that the doctor talked to her son, Mr. Knight,  
25 all on the phone, and that she had had a similar presentation

1 in July. You see where it says that?

2 And Dr. Gunnalaugsson is the cardiologist who said that  
3 they should take a conservative approach. You see that?

4 A. Yes. Yes, I see that in the last paragraph under Plan.

5 Q. Right.

6 A. Yes.

7 Q. Well, let's look at what he says at the bottom: It should  
8 be noted that Dr. Gunnalaugsson did not want her back on  
9 Plavix due to the history of gastrointestinal bleeding.

10 You see where it says that?

11 A. Yes.

12 Q. This cardiologist is afraid to put her on Plavix, right?

13 A. Yes.

14 Q. Because he's worried that what happened in May is going to  
15 happen again, correct?

16 A. Yes.

17 Q. And he says: Will keep her on low-dose aspirin along with  
18 Pradaxa.

19 He's not afraid of Pradaxa at this point in time, correct?

20 A. That's what his note says.

21 Q. Okay. He's afraid of Plavix, correct?

22 A. Yes.

23 Q. And he says: As I do not think Pradaxa could be held in  
24 the long term given her multiple issues with blood clot,  
25 correct?

1 A. The issue here is to compare between the need for Pradaxa  
2 versus Plavix. She passed the month since the stent was put  
3 in, right? Help me out here.

4 Q. Well, let me try to help you out with a couple of  
5 questions, see if we can get those answered first.

6 So this note reflects that Dr. Gunnalaugsson said, ah, did  
7 not want her back on Plavix due to the history of  
8 gastrointestinal bleeding, correct?

9 A. Yes.

10 Q. Plavix could potentially treat a problem that she was  
11 having with the stents at this time if she was having a  
12 problem, correct?

13 A. Correct.

14 Q. Okay. If she was having -- if the cardiologist felt she  
15 was having a problem with the stent, Plavix could help treat  
16 that, right?

17 A. Correct.

18 Q. And Dr. Gunnalaugsson is saying don't do that, I'm afraid  
19 of a bleed, correct?

20 A. Correct.

21 Q. But he is saying go ahead and keep her on Pradaxa because  
22 I'm worried about stroke and blood clots, right?

23 A. Yes.

24 Q. He's not afraid of a bleed with Pradaxa at this point in  
25 time, correct?

1 A. To me that not really is concerning. Because if they  
2 believe this troponin is an indicator of a heart attack, then  
3 she didn't really need the Plavix. Maybe he's just not  
4 convinced of it. Because I wouldn't want somebody bleeding if  
5 they have a heart attack, because they will die first from a  
6 heart attack. So to me, this -- this record really  
7 contradicts itself.

8 Q. My question is this.

9 The physician that was treating her and had seen her many,  
10 many times before this point in time -- right?

11 Dr. Gunnalaugsson --

12 A. Yes.

13 Q. -- a cardiologist --

14 A. Yes.

15 Q. -- in the field of working heart conditions, correct?

16 A. Yes.

17 Q. He concluded to stay on Pradaxa and not take Plavix,  
18 correct?

19 A. Yes.

20 Q. And the reason he made that decision was that he was  
21 afraid that Plavix could trigger a bleed, correct?

22 A. Yes.

23 Q. And he was not afraid of that, according to this note,  
24 with Pradaxa, correct?

25 A. Yes.

1 Q. And in fact, if we go to 9005A-5 --

2 A. 9005A-5.

3 Q. Do you see on 9005-5, we've got a note from August 29 of  
4 2013?

5 A. Yes.

6 Q. And this is from Dr. Gunnalaugsson, and the primary care  
7 physician is Dr. Abdelgaber. And you see: She was  
8 hospitalized with anemia due to GI bleed. She was eventually  
9 surprisingly put back on Pradaxa.

10 You see where it says that?

11 A. Yes.

12 Q. Okay. She has been off Plavix. I have suggested her not  
13 to take aspirin given the situation, correct?

14 A. Yes.

15 Q. That's what it says.

16 Worried about a bleed, correct?

17 A. Yes.

18 Q. Later on, it says: We had done a nuclear stress test last  
19 year, and then she had a coronary intervention earlier this  
20 year.

21 That would be the stent, correct?

22 A. Yes.

23 Q. Okay. And was put on Plavix which probably triggered her  
24 bleed.

25 Right in the record, right? You see that?

1 A. That's what he is saying, yes.

2 Q. That's what he is saying.

3 Plavix triggered the bleed according to this physician who  
4 treated Mrs. Knight during this time frame, correct?

5 A. That's what he says.

6 Q. And you disagree with that?

7 A. No, I'm not saying that. The issue with Pradaxa is how  
8 much you bleed, not what triggers the bleeding. I mean, you  
9 can bleed for 5 or 6 cc's or half a unit. The issue is  
10 life-threatening blood, a hemoglobin of 6.

11 So the trigger could be anything. Anything can -- you  
12 know, it could be the straw that breaks the camel's back.

13 Q. So you agree --

14 A. But it's not because the straw is so heavy. It just  
15 happens to be the back is just about to break.

16 You know, the camel's back is about to break --

17 Q. Doctor --

18 A. -- and you just added a straw.

19 Q. Doctor, yes or no, do you agree with this doctor's  
20 conclusion that Plavix probably triggered her bleed? Yes or  
21 no?

22 A. I can't tell. It could be. I cannot say right or wrong.  
23 It could be.

24 Q. All right. And if we look at 9005-6, which is the next  
25 page.

1 A. Yes.

2 Q. And on August 29th, 2013, this doctor concludes -- this is  
3 9005A-6.

4 A. Yes.

5 Q. She will remain on Pradaxa since she is tolerating this  
6 right now.

7 You know what tolerating means?

8 A. Yes.

9 Q. It's working for her, right?

10 A. That she's able to take it without much problems.

11 Q. Right.

12 She's not experiencing side effects or complications,  
13 right? Correct?

14 A. Yes. That's what he says, yes.

15 Q. And it's working. It's effective for her, right?

16 A. Yes.

17 Q. That's what this doctor is concluding on August 29th of  
18 2013, correct?

19 A. Correct.

20 Q. Yes or no, do you agree with this doctor's conclusion  
21 about Pradaxa being tolerated by Mrs. Knight at this time?

22 A. Tolerated as meaning preventing stroke or not causing side  
23 effects?

24 A. Both.

25 Yes or no, do you agree with this doctor's conclusion or

1 not?

2 A. So far at this point, correct.

3 Q. Okay. Now --

4 MR. LEWIS: I am finished with that exhibit. Just a  
5 couple more topics, Doctor.

6 Q. You have testified that Mrs. Knight was  
7 over-anticoagulated? Is that the right term?

8 A. Yes.

9 Q. Okay. And none of the records that we just reviewed used  
10 the word over-anticoagulated on Pradaxa, do they?

11 A. I did not see it.

12 Q. It's not in there, is it?

13 A. I didn't see it.

14 Q. And you would have pointed that out if it was in there,  
15 wouldn't you have?

16 A. I would have.

17 Q. I figured, yeah.

18 But you base that conclusion on an aPTT test that was run  
19 on May 21st of 2013, correct?

20 A. Yes.

21 Q. After Mrs. Knight had a bleed event that was fixed or  
22 repaired, treated, right?

23 A. Yes.

24 Q. Okay. And you're saying that, based on that aPTT test,  
25 she was over-anticoagulated some day before that?

1 A. Yes.

2 Q. Okay. But you don't have an aPTT test to prove that, do  
3 you?

4 A. The day before, no, I don't.

5 Q. Okay. Or the week before?

6 A. It's true. Whatever is in the record is what I have.

7 Q. Okay. Just the one after --

8 A. Yes.

9 Q. -- of 47?

10 A. Yes.

11 Q. Okay. But you know several times throughout Mrs. Knight's  
12 history with anticoagulant medication, she's been over 47.

13 You know that, right?

14 A. Yes.

15 Q. And in fact, if we go to the aPTT test from opening  
16 statement -- and these are in the record, but this is a  
17 demonstrative.

18 This is a demonstrative that shows in the record all of  
19 the instances where Mrs. Knight, while on warfarin, had  
20 similar or higher aPTT tests, right?

21 A. Yes.

22 Q. On at least six different occasions while on warfarin,  
23 Mrs. Knight had higher or the same -- 46.1. The other five  
24 are higher, right?

25 A. Yes.

Hazem Ashhab - Cross (Lewis)

799

1 Q. The fact is that your conclusion that Mrs. Knight was  
2 over-anticoagulated at the time of a bleed that had apparently  
3 started several days before, the fact is you're guessing,  
4 right?

5 A. Yes.

6 MR. LEWIS: All right. I'm finished with that  
7 exhibit.

8 Q. The last subject, Doctor, is Mrs. Knight passed away on  
9 September 2nd of 2013, correct?

10 A. Yes.

11 Q. Okay. I want to ask you about a document, a medical  
12 document that was associated with that time frame. Okay?

13 A. Yes, sir.

14 MR. LEWIS: I'm going to move for the admission of  
15 9001.

16 (Counsel conferring.)

17 MR. CHILDERS: No objection, Your Honor.

18 THE COURT: It's admitted.

19 (DEFENDANT'S EXHIBIT 9001 ADMITTED INTO EVIDENCE.)

20 BY MR. LEWIS:

21 Q. Doctor, you would agree with me that filling out a  
22 certificate, a death certificate -- have you ever filled out a  
23 death certificate before?

24 A. I did on more than one --

25 Q. You know that is something that is required by law?

1 A. Yes.

2 Q. It is supposed to be accurate, truthful?

3 A. Yes.

4 Q. Okay. And you know Dr. Abdelgaber filled this out for  
5 Mrs. Knight?

6 A. Yes.

7 Q. Okay. And if we look in the center, the doctor has to  
8 indicate what the immediate cause was --

9 A. Yes.

10 Q. -- right?

11 And, again, this isn't something that was covered during  
12 Dr. Abdelgaber's deposition. You probably haven't -- have you  
13 seen this document before?

14 A. I'm not sure.

15 Q. Okay. You see that Dr. Abdelgaber -- that was her  
16 treating physician at the time, right

17 A. Yes.

18 Q. Okay. And he indicates cardiopulmonary arrest.

19 Do you know what that is?

20 A. Yes.

21 Q. That's a heart attack, right?

22 A. The second one is the heart attack.

23 Q. Okay. Cardiopulmonary arrest?

24 A. Is when both the heart and the lungs stop.

25 Q. And due to or as a consequence of acute myocardio

1 infarction, that's a heart attack?

2 A. Yes.

3 Q. And then it also indicates coronary artery disease,  
4 something that Mrs. Knight unfortunately had been struggling  
5 with for a number of years, correct?

6 A. Yes.

7 Q. And what's that last --

8 A. Hyperlipidemia.

9 Q. What is that?

10 A. I think this is just a comorbid condition he listed. It  
11 is when your triglycerides or lipids and cholesterol is  
12 elevated.

13 Q. And you see that other significant conditions attributing  
14 to death are listed even below that, right?

15 A. Yes.

16 Q. And it doesn't appear to have any kind of a limit on how  
17 many can be listed there, right?

18 A. No. You can list as many as you want.

19 Q. And he lists four of them, right?

20 A. Yes.

21 Q. CHF, do you know what that stands for?

22 A. Yeah, congestive heart failure.

23 Q. HTN, hypertension?

24 A. Yes.

25 Q. CKD, chronic kidney disease?

1 A. Kidney disease, correct.

2 Q. And dementia?

3 A. Yes, sir.

4 Q. Dr. Abdelgaber doesn't mention a GI bleed or Pradaxa in  
5 any way, does he?

6 A. Not in this certificate, he does not.

7 MR. LEWIS: I'm finished with that. I just have,  
8 like, five or ten minutes left.

9 Doctor, I just want to ask you about warnings, which  
10 is something that you covered in your direct examination.

11 Q. You've reviewed the Pradaxa label, correct?

12 A. Correct, sir.

13 Q. Okay. And you know that the decisions to put Mrs. Knight  
14 on triple therapy after the stent procedure were made in April  
15 of 2013, right?

16 A. Yes.

17 Q. By physicians other than Dr. MacFarland --

18 A. Yes.

19 Q. -- right?

20 And those physicians had to make that difficult decision  
21 as to whether and how much blood thinner to put Mrs. Knight on  
22 after her stent procedure, right?

23 A. Yes.

24 Q. That was a very difficult choice?

25 A. Yes.

Hazem Ashhab - Cross (Lewis)

803

1 Q. Okay. Sometimes there's no easy answer to some of these  
2 difficult choices on risks and benefits?

3 A. Correct.

4 MR. LEWIS: I don't think 5889 has been admitted, but  
5 that is our label from April of 2013.

6 MR. CHILDERS: No objection.

7 THE COURT: It's admitted.

8 (DEFENDANT'S EXHIBIT 5889 ADMITTED INTO EVIDENCE.)

9 BY MR. LEWIS:

10 Q. So you've reviewed the label for physicians, like the  
11 physicians who would be prescribing triple therapy in April of  
12 2013, for Pradaxa, haven't you?

13 A. Yes.

14 Q. Okay. And there's no question about it in the Warnings  
15 and Precautions, the physicians are well aware and made aware  
16 that there is a serious risk of bleeding, correct?

17 A. Correct.

18 Q. Okay. And there's no question that for those physicians  
19 making that difficult decision in April of 2013, under Drug  
20 Interactions right on the front page: P-gp inhibitors in  
21 patients with severe renal impairment, Pradaxa use is not  
22 recommended.

23 It's right there on the first page, right, Doctor?

24 A. Was that present at the time she was prescribed the  
25 medicine?

Hazem Ashhab - Cross (Lewis)

804

1 Q. I'm talking about in April of 2013.

2 April of 2013, this is --

3 THE COURT: He's referring to tab 5889.

4 MR. LEWIS: You see it was revised --

5 THE COURT: It's in the notebook.

6 THE WITNESS: I see. And at that time it was, yes.

7 BY MR. LEWIS:

8 Q. In April of 2013, those physicians who had to make the  
9 decision to put Mrs. Knight on triple therapy after the stent  
10 procedure, they're going to have this label in April of 2013,  
11 right?

12 A. Yes.

13 Q. And you would agree that they should have read it, right?

14 A. Yes.

15 Q. And a good doctor will read the label periodically, right?

16 A. This label has changed. I think that's the problem here.  
17 Because if you read it one time, you may not know that it was  
18 changed if nobody told you.

19 Q. Doctor, you see that this was a label that was in  
20 existence at the time that Mrs. Knight was prescribed Pradaxa  
21 in April of 2013, correct?

22 A. Correct.

23 Q. All right. And you see that -- you would agree with me  
24 that a good doctor will review labels for medications on  
25 occasion, right?

1 A. Correct.

2 Q. Okay. And right there on the front page, it says recent  
3 major changes. Right on the first page, right?

4 A. Correct.

5 Q. Okay. And this label right on the first page: P-gp  
6 inhibitors in patients with severe renal impairment, Pradaxa  
7 cannot be recommended, correct?

8 A. Correct.

9 Q. Okay. And you would agree with me that a physician who is  
10 prescribing Pradaxa in April of 2013, who read this label,  
11 would know about that risk, correct?

12 A. I would assume so.

13 Q. Okay. And you also agree with me that sometimes doctors  
14 have to make difficult choices to prescribe medication in the  
15 face of risk, right?

16 A. Correct.

17 Q. To avoid other risks, right?

18 A. Correct.

19 Q. And you don't have any criticism, do you, of the doctors  
20 who had to prescribe Mrs. Knight triple therapy in 2013?

21 A. Actually I do.

22 Q. Okay. You don't think they should have put her on triple  
23 therapy?

24 A. The record actually has a little bit of contradiction. On  
25 one side, they said she had a heart attack, but then they go

1 ahead and say we don't want to give her the Plavix, but then  
2 the death certificate says she died of a heart attack. If you  
3 add all these together, it doesn't add up.

4 So I think there is -- I have a couple of issues with  
5 that. If you believe she has a heart attack, and that's the  
6 imminent risk for her, then you should keep Plavix and maybe  
7 stop Pradaxa. But that's not what they did, and they said  
8 because of fear of GI bleeding. But then they say she had  
9 elevated troponin. So I'm a little concerned about that.

10 Q. You would agree with me that the decision that the  
11 physicians had to make in April of 2013 was a difficult one?

12 A. I agree with that.

13 Q. Mrs. Knight had serious risks of blood clots, stroke and  
14 heart disease, correct?

15 A. Correct.

16 Q. And she also had a history of bleeding and anemia,  
17 correct?

18 A. Correct.

19 Q. Okay. And so the decision on what medications to put her  
20 on and how much was a difficult one, correct?

21 A. It was.

22 Q. Okay. But there's no question in your mind that those  
23 physicians should have been aware that there's a risk of  
24 bleeding when those medications were prescribed, correct?

25 A. Correct.

1 Q. Okay. And in fact, if we go to 5889-12, there's a  
2 Medication Guide for Pradaxa, and this is for the patients.

3 And this is also received by those physicians, correct,  
4 5889?

5 A. Yes, the Medication Guide for Pradaxa.

6 Q. Right.

7 And Medication Guides are received by physicians, correct?

8 A. Correct.

9 Q. Okay. And if you look down, scroll down to you may have a  
10 higher risk --

11 A. Yes.

12 Q. -- over 75 years old, that was something that Mrs. Knight  
13 had a higher risk of bleeding --

14 A. Yes.

15 Q. -- correct?

16 Kidney problems, a higher risk of bleeding, correct?

17 A. Yes.

18 Q. And specifically mentions on the fifth bullet point down  
19 Plavix --

20 A. Yes.

21 Q. -- correct?

22 A. Correct.

23 Q. And so the very risk that is contained in this warning  
24 document to physicians and patients occurred with Mrs. Knight,  
25 correct?

1 A. Correct.

2 MR. LEWIS: That's all I have at this time, Your  
3 Honor.

4 (Defense counsel conferring.)

5 MR. LEWIS: Your Honor, actually my co-counsel  
6 indicated that I haven't moved in 9005A, and so I move for the  
7 admission. It's a medical record subset, and I apologize for  
8 that.

9 THE COURT: Any objection?

10 MR. CHILDERS: Not if it's a medical record, Your  
11 Honor.

12 THE COURT: It's admitted.

13 MR. LEWIS: Thank you.

14 (DEFENDANT'S EXHIBIT 9005A ADMITTED INTO EVIDENCE.)

15 THE COURT: All right.

16 REDIRECT EXAMINATION

17 BY MR. CHILDERS:

18 Q. Doctor, I'm going to move up here because I'm going to use  
19 the Elmo to ask you some questions, follow-up questions.

20 Okay?

21 A. Okay.

22 MR. CHILDERS: I'm sorry. Neal knows how to use it,  
23 and I don't. Let me start with this before we get to the  
24 Elmo. I'm sorry.

25 Gina, could you pull up --

1 Q. So this is the label that you were just asked about, that  
2 April of 2013 label, correct?

3 A. Correct.

4 Q. And it says that patients on P-gp inhibitors with severe  
5 renal impairment, Pradaxa use not recommended.

6 Do you see that?

7 A. Correct.

8 Q. And then it tells the physician Section 7 is where they  
9 can go look to get more information, right?

10 A. Yes.

11 MR. CHILDERS: Could you take us to Section 7, Gina.  
12 Blow that up.

13 Q. Tell the jury where it says Coreg or carvedilol in this  
14 section.

15 A. I don't think it is present.

16 Q. Again, you told us earlier Coreg is a common medication  
17 for atrial fibrillation patients?

18 A. Yes, it is.

19 Q. And you told us about it being a P-gp inhibitor.

20 So my question to you is, did you know it was a P-gp  
21 inhibitor before you looked into it for this case?

22 A. Not really.

23 Q. How many P-gp inhibitors are there?

24 A. Oh, a lot, a long list of them.

25 Q. Dozens and maybe more?

1 A. I can only remember the ones that I prescribed in my  
2 medical practice, including the proton pump inhibitors, like  
3 your Prilosec and Prevacid, because I prescribe those. I know  
4 about a couple of antibiotics because I run into those  
5 commonly. But there's a lot of others I didn't even know  
6 about until I read this case.

7 Q. Coreg being one of them?

8 A. Yes.

9 Q. Okay. And if there's a medication that you know is often  
10 given to a patient population who's going to take a medicine  
11 like Pradaxa, do you expect as a physician that the drug  
12 company is going to tell you if there's an interaction with  
13 that drug?

14 A. Yes.

15 Q. Okay. And in this label, does the word Coreg appear  
16 anywhere?

17 A. I don't see it.

18 Q. Does the word -- and carvedilol is the chemical name for  
19 it, the generic name?

20 A. Yeah. I don't see it here.

21 Q. That's not in there either, right?

22 A. No.

23 Q. Okay. Doctor, have you misrepresented anything to this  
24 jury?

25 A. No, not to my knowledge.

1 Q. And do you agree with me it wouldn't be fair for counsel  
2 to misrepresent anything to this jury either, would it?

3 A. That's a question better addressed to him.

4 Q. I'm sorry?

5 A. That is a question to him. It's not good to misrepresent  
6 anything in this courtroom, I believe.

7 Q. You swore to tell the truth. You swore an oath, right?

8 A. Yes.

9 Q. And do you understand the lawyers here, we do that every  
10 day when we walk into court, we have to tell the truth?

11 You understand that?

12 A. Yes.

13 Q. Okay. This chart that Mr. Lewis showed you, he said look  
14 at all of these aPTT readings from when Mrs. Knight, Betty  
15 Knight was on warfarin.

16 Do you remember that?

17 A. Correct.

18 Q. Let me show what those readings actually are. Okay?

19 I'm going to save the first one for last. The first one  
20 says April 9th, 2009. I'm going to save that for last. I'm  
21 going to start with September 16th, 2010.

22 He said the aPTT test was 51. Do you see that on here?

23 A. Yes.

24 Q. And the jury was told that in opening statement, too.

25 Remember he told you that?

1 A. Yes.

2 Q. All right. Let's look at that record.

3 Doctor, is aPTT even measured on this test -- on this  
4 sheet?

5 A. No. That's a pro time INR measurement.

6 Q. That is not an aPTT test, is it?

7 A. No, these are two different things.

8 Q. The PT is part of the INR test, correct?

9 A. The INR is a reflection of the pro time, and this is what  
10 we use to monitor for patients who are on coumadin. The aPTT  
11 is not used to monitor people on coumadin.

12 Q. Okay. Let me show you -- I'll show you again this chart.

13 So the next one that he told you had an aPTT of 16.6 was  
14 June 8th, 2011. Do you see that?

15 A. Yes.

16 Q. Let's look at that record.

17 June 8th, 2011, do they measure the aPTT?

18 A. I don't see it. I see a pro time, PT.

19 Q. And the PT is 16.6, the number that Mr. Lewis told this  
20 jury was her aPTT reading, correct?

21 A. No, these are two different things.

22 Q. Right.

23 All right. Let's look at the next one. 8/17/11, do you  
24 see that the chart says her aPTT was 46.1 that day?

25 A. Yes, I see it.

1 Q. All right. Let's look at that record.

2 46.1, is that the aPTT or the PT?

3 A. I do not see an aPTT here.

4 Q. Okay. That's not the same test, is it?

5 A. No, it's not.

6 Q. Okay. The next one, he says on 10/13 -- I may have missed  
7 one. On 10/13/2011 -- and I'll try to find this one that says  
8 96.2.

9 It says the aPTT was 75.7. Do you see that?

10 A. Yes.

11 Q. Let's look at the test. It's not the test actually. It's  
12 a message from Dr. MacFarland's office.

13 What does she say was 75.7?

14 A. The pro time.

15 Q. Is that the same as the aPTT?

16 A. They are different measurements.

17 Q. Okay. Now I said I was going to save the first one for  
18 last, and there's a reason for that.

19 Do you see that on April 9th, 2009, it says the aPTT was  
20 62 on this chart?

21 A. Yes.

22 Q. And you recall I think in your -- in the deposition of Dr.  
23 Abdelgaber, do you remember he said she had an aPTT of 62 when  
24 she was on Pradaxa when it was measured once, correct?

25 A. Yes.

1 Q. All right. Let's look at that record.

2 Now on this one, they actually did measure her aPTT. Do  
3 you see that?

4 A. Yes.

5 Q. And it was 62, right?

6 A. Yes.

7 Q. What was her INR that day?

8 A. 4.3.

9 Q. Was she over-anticoagulated that day, Doctor?

10 A. Yes.

11 Q. That's a clear sign to you that she was  
12 over-anticoagulated because of the INR, right?

13 A. By all measures.

14 Q. There's no question about that?

15 A. That's true.

16 Q. And her aPTT was 62 that day, correct?

17 A. Yes.

18 Q. I'm going to show you the demonstrative -- not  
19 demonstrative, I'm sorry -- this chart that Mr. Lewis showed  
20 you.

21 Do you recall that?

22 A. Yes.

23 Q. And he asked you didn't her INRs fluctuate during this  
24 time period, correct?

25 A. Yes.

1 Q. Did Betty have a bleed at any point during this time  
2 period?

3 A. Not that was documented, no.

4 Q. And I'm going to get to that in a minute.

5 Did she have a stroke at any point during this time  
6 period?

7 A. No.

8 Q. Does INR fluctuation somehow make Pradaxa an appropriate  
9 medication for a patient with severe renal impairment who is  
10 also taking a P-gp inhibitor?

11 A. That is not enough reason to switch.

12 Q. When Dr. MacFarland actually switched Betty to Pradaxa,  
13 did the label tell her don't give this medicine to a patient  
14 who has severe renal impairment and is taking a P-gp  
15 inhibitor?

16 A. No. It was not in the label at that time. It was added  
17 on later.

18 Q. Did the label ever tell physicians Coreg is a P-gp  
19 inhibitor?

20 A. It does not.

21 Q. I want to show you about the chronic bleed again. This is  
22 is the record you were shown from Dr. Gunnalaugsson from  
23 December 5th, 2008.

24 Can you see that?

25 A. Yes.

Hazem Ashhab - Redirect (Childers)

816

1 Q. That's after the hospitalization where the warfarin was  
2 stopped, correct?

3 Wasn't that in November? I'm sorry, Doctor.

4 A. I believe so, yes.

5 Q. Okay. And he says that it was stopped because of a  
6 chronic bleed.

7 You looked at all of the records themselves, and we went  
8 through them with the jury, correct?

9 A. Yes.

10 Q. Was there any evidence on the record of anyone actually  
11 seeing a bleed?

12 A. No. It was assumed --

13 Q. And we --

14 A. -- but not documented. Nobody found bleeding at that  
15 time.

16 Q. Okay. Let's show you what was shown right early on in  
17 your testimony on cross.

18 This was the coumadin label. Do you remember that?

19 A. Yes.

20 Q. And Mr. Lewis asked you, isn't it true that the bleed  
21 warning is in this box up front? Do you remember that?

22 A. Correct.

23 Q. And I think he asked you, isn't that a good warning.

24 Do you recall that?

25 A. Yes.

1 Q. Wouldn't that be a good warning for Pradaxa to have to  
2 tell doctors that there's a serious, serious risk here and  
3 draw it right to their attention right at the top?

4 A. I believe so.

5 Q. Does it --

6 A. It should be.

7 Q. Does it have a warning like that?

8 A. Not in there. Not in their information, it does not.

9 Q. Okay. I want to ask you about when Betty was switched  
10 from warfarin to Pradaxa. Okay? I'm going to show you these  
11 records that were in the binder that you have up there.

12 The first one was where Rick actually called the office,  
13 and I think we saw this during Dr. MacFarland's deposition,  
14 saying, hey, I'd like to talk to you about a new drug to  
15 replace coumadin.

16 Do you recall that?

17 A. Yes.

18 Q. Okay. And that was on the 17th of October 2011.

19 Do you see that?

20 A. Yes.

21 Q. And then it says: We want to talk before we come in  
22 today. They're coming in at 3:00 today for an appointment.

23 Do you see that?

24 A. Yes.

25 Q. And then we have the record you were shown from that

1 actual appointment, right?

2 A. Yes.

3 Q. The same day, 10/17/11?

4 A. Yes.

5 Q. Where it says want to replace coumadin with new med  
6 Pradaxa, is that under the Chief Complaint section of the  
7 record?

8 Do you see that just above --

9 A. Yes.

10 Q. And then --

11 A. Want to replace coumadin.

12 Q. It says sleeps all the time. Do you see that?

13 A. Yes.

14 Q. The chief complaint section, is that information the  
15 patient gives to the doctor or is that information the doctor  
16 is giving to the patient when you write the chief complaint?

17 A. It's what the patient tells us.

18 Q. Okay. And what does this tell you -- tell us that the  
19 patient said she wanted to replace coumadin with?

20 A. That's what it said.

21 Q. With what?

22 A. With Pradaxa.

23 Q. Specifically asked for Pradaxa?

24 A. Yes.

25 Q. Let me show you this express scrips that we were shown,

1 too, where it was the authorization form for Betty to get  
2 Pradaxa.

3 Do you recall that?

4 A. Yes.

5 Q. And as a doctor, you know that sometimes when you  
6 prescribe a medication, it's not going to be covered, and so  
7 you have to fill out a form to tell the company why you want  
8 it for that particular patient?

9 A. Yes.

10 Q. At the time that -- this is dated October 18th, 2011.

11 At the time that this was written and sent by Dr.  
12 MacFarland, did the Pradaxa label tell her Pradaxa was not an  
13 appropriate medication for a patient with severe renal  
14 impairment who was taking Coreg?

15 A. Not at that time, no.

16 Q. Okay. If a doctor -- you as a doctor, if you were to fill  
17 out one of these forms that said my patient wants to switch  
18 medicine because they say a TV ad, do you expect that the  
19 insurance company is going to cover it for that reason?

20 A. No.

21 Q. All right. Let me show you the Gunnalaugsson record that  
22 you were asked about there at the end.

23 Notes that she had been hospitalized with severe anemia  
24 due to GI bleed, right?

25 A. Yes.

1 Q. And then it says she was eventually surprisingly put back  
2 on Pradaxa. Do you see that?

3 A. Yes.

4 Q. Is that a surprise -- does that surprise you, too?

5 A. Yes. If they assumed there was a GI bleed or they proved  
6 there was a GI bleed, then they shouldn't have put it.

7 Q. And does this tell you what he thought about that?

8 What does it tell you about what he thought about her  
9 being back on Pradaxa when he says surprisingly?

10 A. He said something about the Plavix, which probably  
11 triggered her bleeding.

12 Q. And that's what I wanted to ask you next.

13 Triggering the bleed, you don't dispute that Plavix could  
14 have triggered the bleed, right?

15 A. Could be Plavix or aspirin, either one.

16 Q. Explain to the jury why you think Pradaxa was the most  
17 substantial factor in the bleed and the extent of the bleed  
18 and the damage it did to Betty.

19 A. Anybody can bleed from trivial things. You can cut  
20 yourself when you are shaving or anything. It's the issue of  
21 what stops you or does not stop you from bleeding.

22 I think her blood was too thin than what she had any  
23 reason to bleed whatsoever. In this case, the AVM maybe  
24 touched by the aspirin, then the bleeding would not stop. You  
25 open the faucet, and you cannot stop it because the plug is

1 the fibrin. To make a clot, you need thrombin and fibrin.

2 Well, guess what, the Pradaxa prevents you from making that  
3 clot because it inhibits the thrombin.

4 So you have got a faucet that is oozing. Now it's  
5 bleeding, it is wide open, and you need a plug. Well, the  
6 plug is made of fibrin and thrombin, and Pradaxa prevents  
7 those from working. So the blood is too thin to make the plug  
8 to stop the bleeding.

9 You can trigger the bleeding by anything, but the body has  
10 mechanisms to stop bleeding. In this case, she had Pradaxa  
11 which prevents the body from making the clot or the plug to  
12 stop that faucet that is bleeding. So that's the difference.

13 MR. CHILDERS: Could we go back to the label, Exhibit  
14 No. 88, which was the 2012 label. Page 4, if you could.

15 THE WITNESS: Is that in your folder or --

16 MR. CHILDERS: That's my fault, not yours.

17 Oh, I'm sorry. It's in my folder, yes.

18 THE WITNESS: Your folder. Okay. And direct me to  
19 that page again. I'm sorry.

20 MR. CHILDERS: Exhibit 88, page 4. This is the  
21 Pradaxa label.

22 If you could blow up the very first sentence at the  
23 top, Gina. I'm sorry. The first two sentences. Highlight  
24 that second sentence for me.

25 Q. You had told the jury you thought that Betty Knight likely

1 would not have had a bleed or at least a bleed to the extent  
2 she did if she had been on warfarin.

3 Do you remember that?

4 A. Yes, I do.

5 Q. Okay. I want to show you in the label -- do you see here  
6 where it says: There is a higher rate of major  
7 gastrointestinal bleeds in patients receiving Pradaxa 150  
8 milligrams than in patients receiving warfarin. And then it  
9 says 1.6 versus 1.1.

10 Do you see that?

11 A. Yes.

12 Q. Okay. How does that play into your opinion about whether  
13 or not she would have had a bleed like this on warfarin?

14 A. I believe it would not have been life-threatening like it  
15 was.

16 Q. And how does this particular information, ah, feed into  
17 your --

18 A. That supports my opinion that there is higher incidence of  
19 GI bleeding, gastrointestinal bleeding with Pradaxa compared  
20 with warfarin.

21 In this particular case, we know that she was on warfarin  
22 for years. We know that even if she bled, it would minimum  
23 ooze, never had a life-threatening condition where her  
24 hemoglobin dropped down to 6.

25 So I have the data that supports my opinion that it is

Hazem Ashhab - Redirect (Childers)

823

1 more likely to bleed with Pradaxa than coumadin. From her own  
2 history as a patient, she was on coumadin for years. She did  
3 not have any life-threatening bleeding. She never had  
4 documented bleeding. With Pradaxa, her bleeding almost led to  
5 her demise when her hemoglobin dropped to 6.

6 So that supports my opinion.

7 Q. Can you remind the jury what organs filter Pradaxa out of  
8 your body?

9 A. It is cleared by the kidneys. So when you have kidney  
10 failure or your kidneys are not working well, then you don't  
11 clear the medication out of your system as fast.

12 Q. And warfarin, is that cleared through the kidneys or a  
13 different organ?

14 A. Usually it is metabolized in the liver.

15 Q. Okay. So if you have a patient who has kidney problems,  
16 does that affect their warfarin level like it does with  
17 Pradaxa?

18 A. No. Usually it will affect Pradaxa more.

19 Q. The jury heard, and you read, Dr. MacFarland's deposition.  
20 They heard it this morning when she said that Betty would get  
21 dehydrated sometimes, and that would cause her kidney function  
22 to go down.

23 Do you recall reading that?

24 A. Yes.

25 Q. How is that significant as it relates to her using Pradaxa

1 as an anticoagulant versus warfarin?

2 A. Well, it will affect it, and it will cause a fluctuation  
3 in the level simply because we rely, as physicians, on certain  
4 measurements to tell you how well your kidney is working. And  
5 that blood measurement reflects the function of your kidney at  
6 that point in time when the blood test was done. So if you  
7 are a sick person like Mrs. Knight, and you have multiple  
8 medical problems and episodes of dehydration, then your  
9 kidneys could have been a lot worse than they are when you  
10 came to the doctor.

11 Because usually when you come to the doctor for a routine  
12 visit, you probably will get dressed and have breakfast and  
13 drink. Maybe on a different day, your actual creatinine  
14 clearance will be even much worse, and you will not know it.  
15 So that fluctuation will lead to a fluctuation in the  
16 medication level and the degree of anticoagulation or  
17 over-anticoagulation.

18 It could happen anytime between doctor visit and you not  
19 knowing about it --

20 Q. Anytime --

21 A. -- because you really don't have a way of measuring it.

22 Q. Anytime her kidney function decreased because she was  
23 dehydrated, what would you expect to happen to her Pradaxa  
24 level?

25 A. Probably went up.

1 Q. Okay. And that's based on science, right?

2 A. Yes. Because that's how the medication is cleared out of  
3 your system.

4 Q. Are all anticoagulant medications appropriate for all  
5 patients?

6 A. No.

7 Q. Pradaxa has been on the market now for almost eight years,  
8 right?

9 A. Yes.

10 Q. So have all of the anticoagulant patients switched to  
11 Pradaxa from warfarin?

12 A. No.

13 Q. Well, why is that? Why would patients still use warfarin  
14 if they had Pradaxa available?

15 A. Because of the problems we have been discussing. There  
16 are a certain patient population where Pradaxa or other  
17 anticoagulants are not suitable for them. They may have more  
18 side effects than they will have with coumadin. So it's not  
19 for everybody.

20 Q. You were asked about the Medication Guide. Do you  
21 remember that on cross?

22 A. Yes.

23 Q. I didn't ask you about it on your direct exam, but I want  
24 to ask you about it now since it was brought out in  
25 cross-examination.

1           You read the Medication Guide that Betty and her family  
2           received, right? You read it?

3           A. Yes.

4           Q. Did it tell them that Pradaxa hadn't been tested in  
5           patients like Betty?

6           A. No, it does not say that.

7           Q. Did it tell them that that dose had never been tested?

8           A. It does not.

9           Q. Did it tell them don't take Pradaxa if you take Coreg?

10          A. It does not.

11          Q. Did it tell them don't take Pradaxa if you take any P-gp  
12          inhibitor?

13          A. It does not.

14          Q. Did it tell them that there was no reversal agent for  
15          Pradaxa?

16          A. If does not.

17          Q. Did it tell them that Betty was more likely to have a GI  
18          bleed on Pradaxa than she was on warfarin that she had already  
19          been on?

20          A. I don't believe they told her that.

21                 MR. CHILDERS: I don't have anything else, Your Honor.

22                 MR. LEWIS: May we approach?

23                 THE COURT: Yes.

24                 (Bench conference, reported.)

25                 MR. LEWIS: Maybe I opened the door, but he directly

1 violated the Court's ruling on the 75 and not tested and not  
2 in the Medication Guide. I didn't ask him about that on his  
3 cross-exam. I asked him specific things about the Medication  
4 Guide. I never touched that 75 or that renal function, never  
5 touched it. I think he violated the motion in limine.

6 MR. CHILDERS: He opened the door, Your Honor.

7 THE COURT: How is that?

8 MR. CHILDERS: I didn't talk about the Medication  
9 Guide at all. What he said was this is information that not  
10 only the doctors have, but also the patients have and went  
11 through specific items that are listed in there. And I think  
12 we have a right to say, but things are not listed in there  
13 when he does that on cross-exam.

14 MR. LEWIS: The reason he can't offer those opinions  
15 doesn't change just because I covered that with him. Because  
16 he did offer opinions about the Medication Guide and the  
17 physician label in his report. It was all about risk of  
18 bleed -- everything that I covered was about risk of bleed and  
19 increased risk of bleed. I never touched on 75, and I never  
20 touched renal function.

21 So I get to cross-examine him on the opinions he did  
22 offer, but what I'm not allowed to do is try to cross-examine  
23 him on the 75 or the renal function and then preclude it. I  
24 never touched that, Your Honor.

25 MR. CHILDERS: May I?

Hazem Ashhab - Redirect (Childers)

828

1 THE COURT: Yes.

2 MR. CHILDERS: He didn't offer opinions on the  
3 Medication Guide in his report or in his deposition. He  
4 opened the door on that. We had this discussion before.

5 THE COURT: He didn't open the door that you raised in  
6 the motion, so I do think that you violated the order. The  
7 question is now what is the remedy you'd like to suggest to  
8 the Court?

9 MR. LEWIS: Can we give that some thought? I mean,  
10 it's already out.

11 THE COURT: Are you finished with him?

12 MR. CHILDERS: Yes.

13 MR. LEWIS: I have very brief recross.

14 THE COURT: So --

15 MR. LEWIS: I don't want to touch it on recross.

16 THE COURT: One option would be that the Court can  
17 instruct the jury that to the extent what was commonly a  
18 failure of the label to test the 75 dose or testing of  
19 patients with severe renal problems, the expert is not  
20 offering an opinion that the label is deficient based on that.  
21 That's outside the scope of his opinions.

22 MR. LEWIS: And they can't consider it.

23 MR. CHILDERS: That's fine.

24 THE COURT: Okay.

25 MR. LEWIS: They can't consider it.

Hazem Ashhab - Redirect (Childers)

829

1 THE COURT: I don't want to say you can't -- yeah,  
2 they might get confused. You can't consider the fact even if  
3 established by some other expert's opinion?

4 The point is to say this witness wasn't offering an  
5 opinion that the label was deficient for failure to report in  
6 the label the 75 dose testing or the testing on patients with  
7 severe renal problems.

8 MR. LEWIS: Okay. The instruction works out. You  
9 need to put the flip chart away.

10 MR. CHILDERS: Sure.

11 THE COURT: All right. So do you want me to give this  
12 instruction first and then you're going to recross or after  
13 you recross?

14 MR. LEWIS: How about after recross?

15 THE COURT: Okay.

16 MR. CHILDERS: Thank you.

17 (Bench conference, concluded.)

18 THE COURT: All right. I think we're almost done with  
19 this witness. Are you folks okay for another five or ten  
20 minutes to do that?

21 Okay. Great. That will save us time in the long run,  
22 I believe.

23 All right. Recross.

24 MR. LEWIS: Yes, Your Honor, very briefly.

25 Thank you, Members of the Jury and Dr. Ashhab for

1 hanging in there today. I appreciate trying to get you  
2 finished up.

3 RECROSS-EXAMINATION

4 BY MR. LEWIS:

5 Q. The first thing I need to do is stand corrected. You  
6 pointed out a mistake that I made in a slide that I created  
7 last night before I examined you, and that was with respect to  
8 the aPTT levels. So I do want to cover the documents that you  
9 covered with Mr. Childers, though, because I clearly misread  
10 the medical records.

11 But I think I read something correctly, and I just want to  
12 make sure that I get it correct. Okay?

13 A. Okay.

14 MR. LEWIS: I'm going to go to 9009A.

15 Q. And these are corresponding to those dates that you  
16 covered with Mr. Childers on the PT levels.

17 A. Yes, sir.

18 Q. And the first one I want to cover is 179, 9009A-179.

19 A. Yes.

20 Q. Definitely there's a PT test. That's not aPTT, right?

21 A. Yes.

22 Q. A different test.

23 But there is an INR reading?

24 A. Yes.

25 Q. And the INR reading is elevated, correct?

1 A. Correct.

2 Q. Okay.

3 (Off the record.)

4 BY MR. LEWIS:

5 Q. That's elevated. That's a higher risk of bleed at that  
6 time?

7 A. Correct.

8 Q. Okay. If we go to 9009-206, that was another one  
9 mentioned on that slide.

10 A. Correct.

11 Q. There we do have an aPTT level at 62, right?

12 A. Yes.

13 Q. That's elevated, correct?

14 A. Yes.

15 Q. And if you go down to the INR, that is 4.3. That is  
16 elevated, correct?

17 A. Correct.

18 Q. Okay. If we go to -- the next one that I mentioned was in  
19 383. There's that PT again. That is 75.7.

20 That's not aPTT, correct?

21 A. One more time the page, please?

22 Q. 383. Sorry. Thank you, Doctor.

23 A. Yes, sir.

24 Q. Okay. But the INR is elevated, and that is 6.3?

25 A. Correct.

1 Q. Higher risk of bleed?

2 A. Correct.

3 Q. The next one is 389.

4 There is no aPTT test there, correct?

5 A. Correct.

6 Q. But there is an INR test. That is at 8.0 on October 10,  
7 2011.

8 A. Correct.

9 Q. That is significantly elevated, correct?

10 A. Correct.

11 Q. Okay. The next one is 9009-451. Again, not aPTT, my  
12 mistake. But there is an INR, and that is elevated again,  
13 correct?

14 A. Yes.

15 Q. Okay. And the last one is 461. Again, no aPTT, my bad.  
16 But the INR is measured, and that is elevated again, correct?

17 A. Correct.

18 Q. Okay. I apologize for the mistake that I made in the  
19 slide, but the records do reflect that on each of the  
20 occasions that we've just discussed, Mrs. Knight was at a  
21 higher risk of bleed because of her higher INR levels on  
22 warfarin, correct?

23 A. Correct.

24 Q. Okay. The last thing I want to discuss is the Pradaxa  
25 physician label. That is Exhibit 5889.

1 And first of all, if you look at the Warnings and  
2 Precautions, risk of bleeding is on the first page of the  
3 physician label, correct?

4 A. Correct.

5 Q. Any physician who is prescribing anticoagulant medication  
6 is going to understand there is a significant risk of bleeding  
7 when prescribing that medication, right, Doctor?

8 A. Correct.

9 Q. Does it matter whether it's on the left side or the right  
10 side on the first page of the physician label?

11 A. No, but there is a box where something kind of attracts  
12 your attention more. So you pay attention if you see it  
13 outlined or in bold. But whether it is on the right or the  
14 left, no.

15 Q. On page 5889-04, there is -- this is a physician label.

16 By the way, do you read physician labels?

17 A. I read them when it pertains to a certain patient's risk,  
18 yes.

19 Q. Right.

20 And do you sometimes read study results?

21 A. I do.

22 Q. Okay. And do you take those into account when you're  
23 prescribing medication for your patients?

24 A. That's correct.

25 Q. And you understand that some medications have higher risks

1 of one thing and lower risks of another?

2 A. Correct.

3 Q. And you, as a physician, have to take those -- the menu  
4 unfortunately of risks that come with a medication and factor  
5 that into your decision, right?

6 A. Correct.

7 Q. And then you also have to understand the benefits of a  
8 particular medication, right?

9 A. Correct.

10 Q. Okay. And you know that BI, Boehringer ran a clinical  
11 trial called the RE-LY study that is reflected in this label,  
12 right?

13 A. Yes.

14 Q. And that study did reflect, as indicated here, there was a  
15 higher rate -- right under the chart, the second paragraph --  
16 there was a higher rate of major gastrointestinal bleeds in  
17 patients receiving Pradaxa.

18 That's the higher dose, the 150, right?

19 A. Yes.

20 Q. That is right in the physician label, right?

21 A. Yes.

22 Q. There are no secrets here.

23 Boehringer is telling physicians, in our trial, we did  
24 have a higher rate of major gastrointestinal bleeds, correct?

25 A. Yes.

1 Q. That's what they should be telling physicians if that is  
2 what the data shows, correct?

3 A. Correct.

4 Q. But you also know that in that same chart that is just  
5 above there, Pradaxa performed better in a different type of  
6 risk, correct?

7 A. Correct.

8 Q. Do you know what a brain bleed is?

9 A. Yes.

10 Q. And that's what is referred to when it's intracranial  
11 hemorrhage?

12 A. Yes.

13 Q. Okay. You see Pradaxa had a lower risk of that particular  
14 complication, right?

15 A. Yes.

16 Q. And brain bleeds or intracranial hemorrhages can be very,  
17 very serious complications, too, right?

18 A. Yes.

19 Q. So these physicians have to make this choice, well, I've  
20 got a lower risk of a brain bleed, but maybe a higher risk of  
21 a GI bleed.

22 Those are the choices that physicians have to make when  
23 they are assessing an individual patient, right?

24 A. Correct.

25 Q. And one physician may choose to avoid the brain bleed and

1 take the high risk of a gastrointestinal bleed, correct?

2 A. Depending on the clinical scenario, and each particular  
3 patient is unique.

4 Q. Right.

5 And if we look at 5889-08, you also know, don't you, that  
6 that RE-LY study, as this chart reflects, showed that Pradaxa  
7 had a lower risk of stroke events as compared to warfarin in  
8 that trial, right?

9 A. Yes.

10 Q. That's a benefit, right?

11 A. Yes.

12 Q. So when we look at the full menu of risks and benefits,  
13 we've got three things to consider at least, right? We've got  
14 to consider that in the trial Pradaxa offered better stroke  
15 protection, correct?

16 A. Yes.

17 Q. Better avoidance of risk of brain bleed, correct?

18 A. Yes.

19 Q. But at a higher risk of GI bleed, correct?

20 A. Correct.

21 Q. And so the physician has to balance those things, among  
22 others, when prescribing Pradaxa to a patient, correct?

23 A. In general.

24 Q. Okay. In general?

25 A. For Mrs. Knight, it was the wrong drug to start with.

1 Q. Understood.

2 But her physicians might have chosen -- we know this.

3 We know that she didn't have a stroke while she was on  
4 Pradaxa, correct?

5 A. Correct.

6 Q. We know that she didn't a brain bleed while she was on  
7 Pradaxa, correct?

8 A. Correct.

9 Q. And those things could have been way more important to her  
10 physicians than the GI bleed risk, correct?

11 A. But that's not what the case turned out to be.

12 Q. Understood.

13 A. That's the problem. It's -- what you're talking about  
14 here is all correct for the general population, maybe for the  
15 majority of the population. The problem we face here with  
16 Mrs. Knight is she's in that minority of population who has  
17 multiple medical problems, kidneys are not working properly,  
18 taking medications that interfere with the medicine. So she  
19 is, in my opinion, the wrong patient to take that medication.

20 I'm not saying the medication is a bad medication. It's a  
21 very good medication, but I think it was given to the wrong  
22 person. I think there ought to be something to tell the  
23 physician don't give this drug to this patient.

24 It is probably good for the next person, the next ten  
25 people after Mrs. Knight. But for her, I think it was the

1 wrong medicine, and I think the doctors were not fully  
2 informed that they shouldn't have given her the medicine.  
3 That's all what I'm trying to say.

4 Q. Doctor, yes or no, Mrs. Knight's physicians could have  
5 chosen to take the risk of the GI bleed to get the benefits of  
6 better stroke protection and the avoidance of a brain bleed.

7 That's a choice that her physicians might have made,  
8 correct? Yes or no?

9 A. The issue is I don't know if they were fully informed  
10 about these risks.

11 I mean, we're not really comparing apples with apples here  
12 because the risk of stroke in atrial fibrillation is less than  
13 5 percent anyway. But the risk of bleeding may be a lot more  
14 in somebody with poor creatinine clearance who takes Coreg.  
15 So it's not comparing apples with apples and saying it's a  
16 bleed in the brain or in the colon. No, the likelihood of  
17 having that event is very different.

18 So you're trying to prevent a stroke. Well, what are the  
19 chances of getting a stroke in an AFib patient? It's 2 to 3  
20 percent, less than 5 percent anyway.

21 Q. Can you answer my question, Doctor?

22 A. Yes, sir.

23 Q. Okay. I'll give it another run.

24 Mrs. Knight's physicians, when choosing to put her on  
25 Pradaxa in April of 2013 and combine it with Plavix and

1 aspirin, could have been choosing to avoid the risk of brain  
2 bleed, get the benefit of stroke protection and take on the  
3 risk of gastrointestinal bleeding? That's the choice that  
4 they could have made at that time, correct?

5 A. They could have.

6 Q. Okay. And isn't it true that you, in your practice,  
7 Doctor, don't make those type of risk-benefit decisions for  
8 anticoagulant medication.

9 You don't prescribe anticoagulant medication, do you?

10 A. But I do participate in these decisions. When somebody  
11 has GI bleeding, then I'm part of the team. It's a  
12 consultation between the cardiologist, the primary care  
13 physician and the gastroenterologist to reach what you just  
14 talked about, what is the best medicine for that person.

15 Q. That's not my question.

16 You don't prescribe anticoagulant medication, and so you  
17 don't make the ultimate risk and benefit determination for  
18 those patients, correct?

19 A. Partially correct. I do not prescribe the medication, you  
20 are correct.

21 Q. Thank you, Doctor.

22 A. I do contribute to the decision to prescribe.

23 MR. LEWIS: Thank you for your time.

24 THE WITNESS: Thank you.

25 THE COURT: All right. Any --

1 MR. CHILDERS: Judge, can we see you one more time?

2 THE COURT: Yes.

3 (Bench conference, reported.)

4 THE COURT: So make sure you use the microphone.

5 MR. CHILDERS: To address this issue with the testing,  
6 he just went through the RE-LY study results with him that  
7 don't include the 75 milligram or severe renal patients.  
8 Right after we just had this discussion, and we agreed we were  
9 going to give a limiting instruction, he went into trying to  
10 convince the doctor to tell the jury that a patient is better  
11 off on Pradaxa than warfarin when it hasn't been tested at  
12 that dose.

13 MR. LEWIS: No, he testified on redirect about the  
14 gastrointestinal bleed increase. He covered the very same  
15 line that I just addressed with him, and my only rebuttal to  
16 that was there's more than one risk to consider. I never  
17 talked about the dosage.

18 THE COURT: Okay. I agree with the defendant.

19 MR. CHILDERS: Fair enough, Your Honor. Thank you.

20 MR. LEWIS: Thank you.

21 (Bench conference, concluded.)

22 THE COURT: All right. Doctor, that concludes your  
23 testimony. Thank you. You may step down.

24 THE WITNESS: Thank you.

25 THE COURT: All right. Ladies and Gentlemen, there's

1 one matter I need to instruct you concerning.

2 At the close of the redirect examination by  
3 Mr. Childers, if you recall, he used the handwritten chart  
4 that he had developed in his opening statement, and he walked  
5 through that chart with Dr. Ashhab, asking him about opinions  
6 with respect to the adequacy, the sufficiency of the label as  
7 to each of those points.

8 An expert in a case is required to disclose opinions  
9 in advance of trial, and the Court has determined here that  
10 two of the opinions that he offered in that brief questioning  
11 were not opinions that he had offered during the course of his  
12 disclosures of his expert opinions. So I want to give you an  
13 instruction concerning those.

14 Specifically on that chart, it was noted in response  
15 to plaintiffs' counsel's questions that there was, first, what  
16 he considered a failure to include as a warning in the label  
17 the fact that Pradaxa was not tested on people with severe  
18 renal impairments. Secondly, he also testified an opinion  
19 that the label was inadequate because the testing was not done  
20 on people taking -- in studies, on people taking 75-milligram  
21 doses.

22 The Court would find and instruct that those were two  
23 opinions that were outside of his disclosure. To the extent  
24 plaintiff is relying upon those as evidence of a defect, they  
25 have to get that evidence from other witnesses besides Dr.

1 Ashhab. Dr. Ashhab is not permitted to testify to those two  
2 specific opinions because he didn't disclose them before. If  
3 the plaintiff make arguments about those alleged failures of  
4 the label, they have to depend upon someone other than Dr.  
5 Ashhab for that testimony.

6 Do counsel have any quarrel with the instruction that  
7 I've given?

8 MR. CHILDERS: No, Your Honor.

9 MR. LEWIS: No, Your Honor.

10 THE COURT: All right. With that, Ladies and  
11 Gentlemen, that concludes our work for today. I'm going to  
12 excuse you until 9:00 a.m. tomorrow.

13 Remember, as we have done throughout the trial, I'm  
14 ordering that you not discuss the case with anyone or try to  
15 do any investigation or look into any matters on your own.  
16 With that, I'll see you back here at 9:00 a.m. tomorrow.

17 I do have one brief housekeeping measure to take up  
18 with counsel. If you can stick around, it will only take a  
19 minute. The jury is excused.

20 (Jury not present.)

21 THE COURT: As the jury leaves, I want to clarify with  
22 counsel a couple of the exhibits.

23 Mr. Lewis, you used in your examination an exhibit  
24 that is the -- I don't remember if it has a number, but it's a  
25 colored chart that shows the INR values up and down. You said

1 that you were offering that chart into evidence under Rule  
2 1006. And then either in the exchange or in response to  
3 Mr. Childers' objection, you said that you have an exhibit  
4 which I've seen that purports to be a summary of all of the  
5 medical records that include or are included in the INR  
6 reporting history, and that has been marked as Exhibit 9009S.

7 MR. LEWIS: Yes.

8 THE COURT: And so as I understand the rule, I think  
9 if counsel for the plaintiffs has no objection to the accuracy  
10 of the 9009S chart, that it's admissible under 1006 as a chart  
11 or summary based upon voluminous documents that can be  
12 admitted into evidence to establish the contents of the  
13 document.

14 And as I understood it, these are documents, medical  
15 records that have been obtained through the certification  
16 process and, as I understood it, disclosed to plaintiffs  
17 beforehand. If that's not the case, then we need to address  
18 that.

19 But it seems to me that this chart and the  
20 accompanying medical records may be admitted as one exhibit.  
21 But I considered the first chart that you had to be a  
22 demonstrative aid, which is not admitted into evidence.

23 MR. LEWIS: Correct.

24 THE COURT: So is that the way you offer and intend to  
25 use these two different documents?

1 MR. LEWIS: Yes. The color chart is a demonstrative  
2 only. The more generic chart with the numbers in it was the  
3 summary --

4 THE COURT: Okay.

5 MR. LEWIS: -- for admission.

6 THE COURT: Right. Okay.

7 MR. CHILDERS: Thank you, Your Honor.

8 The only thing I would ask is we did get that, but it  
9 was today. I'm certain it's probably right. If you would  
10 just give us overnight to look at it --

11 THE COURT: I'll withhold ruling on the admissibility  
12 of 9009S until plaintiffs have had a chance to review the  
13 underlying records.

14 MR. CHILDERS: Thank you, Your Honor.

15 THE COURT: In any event, the first chart you used is  
16 a demonstrative aid only.

17 MR. LEWIS: Correct.

18 THE COURT: All right. Thanks for clearing it up.

19 Is there anything else we need to take up today?

20 MR. CHILDERS: We have many exhibits that came in  
21 today, and we talked to Terry about doing those first thing in  
22 the morning because it's a little late.

23 Is that --

24 THE COURT: Sure. That's fine.

25 MR. CHILDERS: Thank you, Your Honor.

1 MR. LEWIS: Thank you.

2 THE COURT: See you back here at 9:00 a.m. tomorrow.

3 Let's try to start about five minutes early, if you  
4 don't mind. If we've got all of the jurors back here, we can  
5 do the exhibits then.

6 MR. CHILDERS: Yes.

7 THE COURT: Thank you.

8 THE COURT SECURITY OFFICER: All rise. This honorable  
9 court will be adjourned.

10 (Proceedings were adjourned at 5:34 p.m.)

11 ---o0o---

12

13

14

15

16

17

18

19

20

21

22

23

24

25

1 CERTIFICATION:

2 We, Kathy L. Swinhart, CSR, and Lisa A. Cook,  
3 RPR-RMR-CRR-FCRR, certify that the foregoing is a correct  
4 transcript from the record of proceedings in the  
5 above-entitled matter as reported on October 9, 2018.

6  
7  
8 October 10, 2018  
9 DATE

10 /s/ Kathy L. Swinhart  
11 KATHY L. SWINHART, CSR

12 /s/ Lisa A. Cook  
13 LISA A. COOK, RPR-RMR-CRR-FCRR  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25